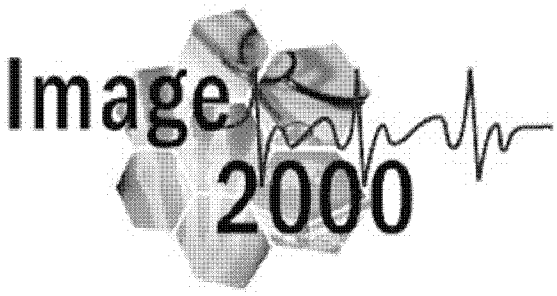

USER: RITCHWOOD, JASMINE M (jmr)

FOLDER: K002321 - 50 pages (FOI:08007513)

COMPANY: BREG, INC. (BREG)

PRODUCT: PUMP, INFUSION, ELASTOMERIC (MEB)

SUMMARY: Product: PAIN CARE 2000L

DATE REQUESTED: Fri Sep 03 24:00:00 2010

DATE PRINTED: Wed Oct 27 10:27:01 2010

Note: Releasable Version

Table of Contents

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2000

Ms. Kathleen Barber
Vice President of Regulatory Affairs
Breg, Incorporated
2611 Commerce Way
Vista, California 92083

Re: K002321
Trade Name: Pain Care 2000L
Regulatory Class: II
Product Code: MEB
Dated: July 28, 2000
Received: July 31, 2000

Dear Ms. Barber:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Intended Use

BREG's Pain Care 2000L is intended to provide patient controlled intermittent infusion of a local anesthetic into an intra-operative site for the post-operative management of pain.

The purpose of BREG's Pain Care 2000L is to provide a delivery mechanism of local anesthetic maintenance doses in order to sustain pain relief that is initially established by the bolus of local anesthetic that is injected intra-operatively (loading dose).

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
(ODE) Number K002321

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 5/14/2000

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K002321/A1

To: Division Director: HFZ/DJCG

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

✓ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____Additional information requires a new 510(k); however, the information submitted is incomplete; (Noitify company to submit a new 510(k);[Prepare the K30 Letter on the LAN]

_____Additional information requires a new 510(k); please process [This information will be made into a new 510(k)

_____No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440_

_____Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

____Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

_____No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: SWF

Date: _____

Draft #2 : 9/8/99
Draft #3: 1/3/00

AUG 11 7 2000
DMC

K002321/A1

BREG

2611 Commerce Way
Vista, CA 92083

SP 29

RECEIVED
14 AUG 00 13 02
FDA/CDRH/ODE/DMC

BY PRIORITY MAIL

August 10, 2000

Document Mail Center(HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

RE: Pain Care 2000L K002321

Attn.: Sarah Foster

As you requested, I have modified and attached the following documents:

- Page 7: Indications for Use have been modified to include a statement that the use of the 2000L is the same as that of the 2000
- Page 8: The table has been modified to include a description of how the change works
- Page 9: The material for the flow restrictor tubing and catheter is polyurethane. This has been added to the drawing.

Please direct all correspondence regarding this submission to me at the letterhead address. If you have any questions which may be appropriately answered by phone, then please telephone my office at (760) 599-5719, during the hours of 8:30AM - 5:00PM, PST. Thank you for your attention to this document.

Sincerely yours,

Kathleen Barber
Vice President of Regulatory Affairs

Enclosures: 2 copies changes with cover letter attached

STATEMENT OF INDICATIONS FOR USE

Intended Use

BREG's Pain Care 2000L has the same intended use as BREG's Pain Care 2000. Both units are intended to provide patient controlled intermittent infusion of a local anesthetic into an intra-operative site for the post-operative management of pain.

The purpose of BREG's Pain Care 2000 and 2000L is to provide a delivery mechanism of local anesthetic maintenance doses in order to sustain pain relief that is initially established by the bolus of local anesthetic that is injected intra-operatively (loading dose).

Comparison of Features Pain Care 2000L v. Pain Care 2000

Device Name	Pain Care 2000L	Pain Care 2000
Manufacturer	BREG, Inc.	BREG, Inc.
Type	Patient Controlled, Spring Loading Syringe Injected, Single Patient Use	Patient Controlled, Spring Loading Syringe Injected, Single Patient Use
Capacity	50 cc	50 cc
Rate	4 cc per Injection, no more than 12cc per hour	4 cc per Injection
Flow control	Flow Restrict tubing for Syringe Filling. The addition of a length of tubing with small internal diameter limits the amount of fluid that enters the system, controlling the rate to no more than 12cc per hour.	Flow Restrictor for Syringe Filling,
Duration	2-3 Days	2-3 Days
Applications	Procedures requiring local analgesic non-narcotic pain relief.	Procedures requiring local analgesic non-narcotic pain relief.
Contraindications	Not designed for epidural, subcutaneous or vascular drug delivery. Not for blood, blood products or TPN use.	Not designed for epidural, subcutaneous or vascular drug delivery. Not for blood, blood products or TPN use.
Benefits	Direct pain relief w/o side effects of narcotics, decreased breakthrough pain, reduced hospital stay, earlier ambulation and greater range of motion.	Direct pain relief w/o side effects of narcotics, decreased breakthrough pain, reduced hospital stay, earlier ambulation and greater range of motion.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 4 2000

Ms. Kathleen Barber
Vice President of Regulatory Affairs
Breg, Incorporated
2611 Commerce Way
Vista, California 92083

Re: K002321
Trade Name: Pain Care 2000L
Regulatory Class: II
Product Code: MEB
Dated: July 28, 2000
Received: July 31, 2000

Dear Ms. Barber:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

Intended Use

BREG's Pain Care 2000L is intended to provide patient controlled intermittent infusion of a local anesthetic into an intra-operative site for the post-operative management of pain.

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002321

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: 8/11/00 Reviewer(s) - Name(s) Sarah Foster

Subject: 510(k) Number K002321

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☒ Is substantially equivalent to marketed devices.
- ☐ NOT substantially equivalent to marketed devices.
  - De Novo Classification Candidate? ☐ YES ☐ NO
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐ YES	☒ NO
Is this device subject to the Tracking Regulation?	☐ YES	☒ NO
Was clinical data necessary to support the review of this 510(k)?	☐ YES	☒ NO
Is this a prescription device?	☒ YES	☐ NO
Was this 510(k) reviewed by a Third Party?	☐ YES	☒ NO
Special 510(k)?	☒ YES	☐ NO
Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers	☐ YES	☒ NO

This 510(k) contains:

Truthful and Accurate Statement ☐ Requested ☒ Enclosed
(required for originals received 3-14-95 and after)

- ☐ A 510(k) summary OR ☒ A 510(k) statement
- ☐ The required certification and summary for class III devices n/a
- ☒ The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin ☐ YES ☒ NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

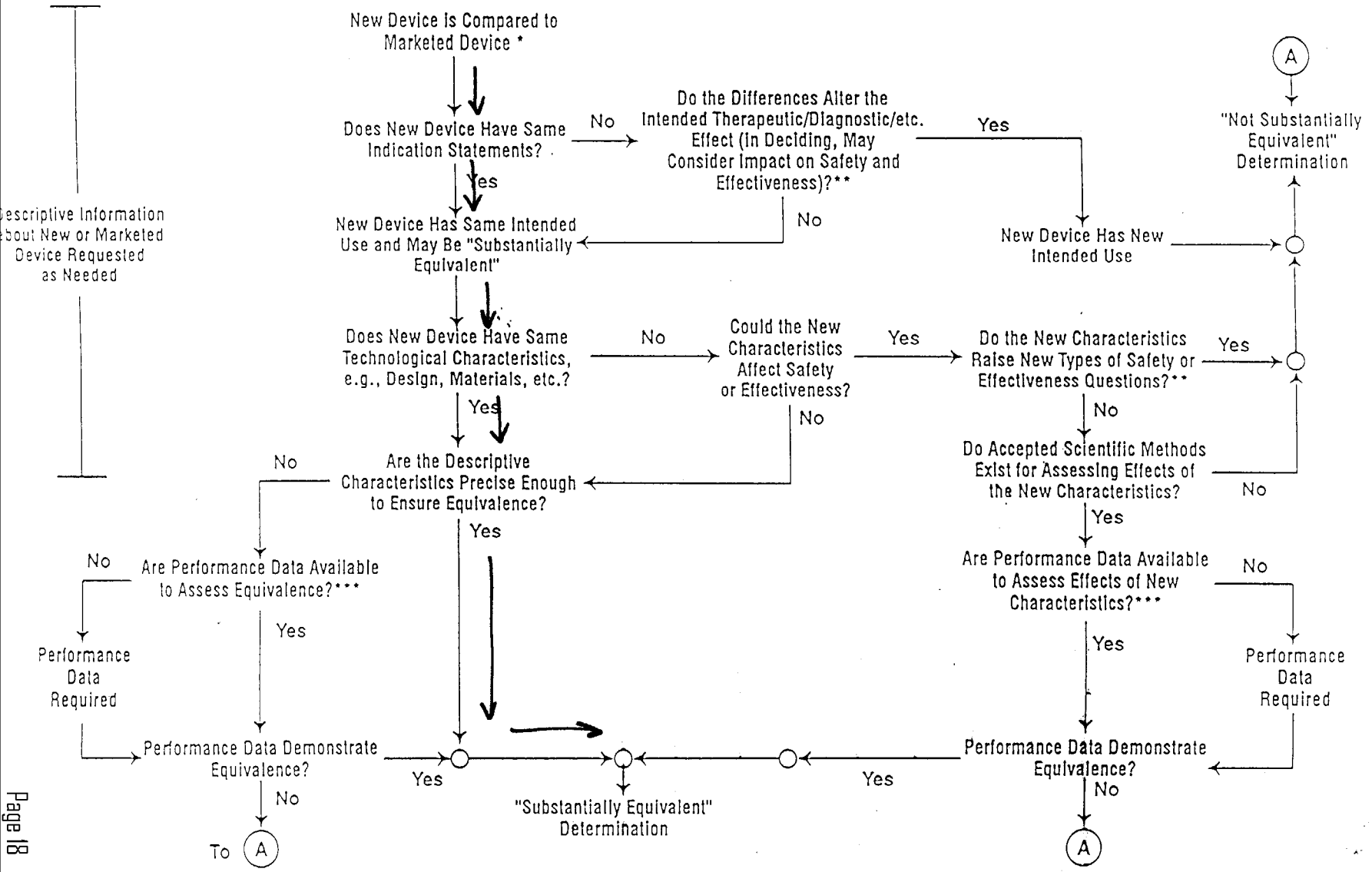
Predicate Product Code with class: 80/MEB II

Additional Product Code(s) with panel (optional):

Review: Patricia Cucuzza (Branch Chief) HFDB (Branch Code) 5/4/00 (Date)

Final Review: (Division Director) 8/14/00 (Date)

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendment or Reclassified Post-Amendments) Devices Is Unclear.

** This Decision Is Normally Based on Descriptive Information Alone, But Limited Testing Information Is Sometimes Required.

*** Data From 510(k), Other 510(k)s, The Center's Classification Files, or the Literature.

SPECIAL 510(k): Device Modification
ODE Review Memorandum

To: THE FILE **RE:** DOCUMENT NUMBER K 002321

This 510(k) submission contains information/data on modifications made to the SUBMITTER'S own Class II, Class III or Class I devices requiring 510(k). The following items are present and acceptable (delete/add items as necessary):

1. The name and 510(k) number of the SUBMITTER'S previously cleared device. (For a preamendments device, a statement to this effect has been provided.)
2. Submitter's statement that the **INDICATION/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials.
3. A description of the device **MODIFICATION(S),** including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed.**

   This change was for the addition of flow control, limiting the flow rate to 12cc per hour.
4. **Comparison Information** (similarities and differences) to applicant's legally marketed predicate device including, labeling, intended use, physical characteristics, and pump type, flow control, rate, applications, contraindications, and benefits .
5. A **Design Control Activities Summary** which includes:
   a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis
   b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied
   c) A declaration of conformity with design controls. The declaration of conformity should include:
      i) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met, and
      ii) A statement signed by the individual responsible, that the manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30 and the records are available for review.
6. A **Truthful and Accurate Statement**, a **510(k) Summary or Statement** and the **Indications for Use Enclosure (and Class III Summary for Class III devices).**

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or theirpreamendment) device.

Sarah Foster
(Reviewer's Signature)

8/11/00
(Date)

Comments
This Special 510(k) includes only the minimum amount of information necessary for a Special 510(k) submission. However, since the only change made was the minor addition of flow restricting tubing as a safety element, this submission is acceptable. I recommend theBreg Pain Care 2000L be determined substantially equivalent to the predicate device, the Breg Pain Care 2000 .

revised:3/27/98

Memo

To: The File

From: Sarah Foster, Reviewer

Date: 08/10/00

Re: Document Number K002321

Memo Regarding Telephone Conversation on 8/04/00

This memo confirms the telephone conversation held at 12:30pm on 8/04/00 between Kathleen Barber of Breg, Inc. and Sarah Foster of DDIGD/GHDB. A request to Ms. Barber was made to send a document stating that the indications for use for the Breg 2000L have not changed from the predicate device, the Breg 2000. Clarification on the flow rate restriction was also requested. These items were faxed to DDIGD on 8/7/00, and will be added to the Special 510(k) 002321. A hard copy will follow.

Sarah Foster

2611 Commerce Way
Vista, CA 92083

BY FAX: 301.480.3002

DATE: August 7, 2000

Attn: Sarah Foster

RE: Pain Care 2000L K002321

Thank you for your telephone call of Friday, August 4, 2000.

As you requested, I have modified and attached the two following documents:

- Page 7: Indications for Use have been modified to include a statement that the use of the 2000L is the same as that of the 2000
- Page 8: The table has been modified to include a description of how the change works

If you have any questions which may be appropriately answered by phone, then please telephone my office at (760) 599-5719, during the hours of 8:30AM - 5:00PM, PST. Thank you for your attention to this document.

Sincerely yours,

Kathleen Barber
Vice President of Regulatory Affairs

STATEMENT OF INDICATIONS FOR USE

Intended Use

BREG's Pain Care 2000L has the same intended use as BREG's Pain Care 2000. Both units are intended to provide patient controlled intermittent infusion of a local anesthetic into an intra-operative site for the post-operative management of pain.

The purpose of BREG's Pain Care 2000 and 2000L is to provide a delivery mechanism of local anesthetic maintenance doses in order to sustain pain relief that is initially established by the bolus of local anesthetic that is injected intra-operatively (loading dose).

Comparison of Features Pain Care 2000L v. Pain Care 2000

Device Name	Pain Care 2000L	Pain Care 2000
Manufacturer	BREG, Inc.	BREG, Inc.
Type	Patient Controlled, Spring Loading Syringe Injected, Single Patient Use	Patient Controlled, Spring Loading Syringe Injected, Single Patient Use
Capacity	50 cc	50 cc
Rate	4 cc per Injection, no more than 12cc per hour	4 cc per Injection
Flow control	Flow Restrict tubing for Syringe Filling. The addition of a length of tubing with small internal diameter limits the amount of fluid that enters the system, controlling the rate to no more than 12cc per hour.	Flow Restrictor for Syringe Filling,
Duration	2-3 Days	2-3 Days
Applications	Orthopedic procedures requiring local analgesic non-narcotic pain relief.	Orthopedic procedures requiring local analgesic non-narcotic pain relief.
Contraindications	Not designed for epidural, subcutaneous or vascular drug delivery. Not for blood, blood products or TPN use.	Not designed for epidural, subcutaneous or vascular drug delivery. Not for blood, blood products or TPN use.
Benefits	Direct pain relief w/o side effects of narcotics, decreased breakthrough pain, reduced hospital stay, earlier ambulation and greater range of motion.	Direct pain relief w/o side effects of narcotics, decreased breakthrough pain, reduced hospital stay, earlier ambulation and greater range of motion.

Memo

To: The File

From: Sarah Foster, Reviewer

Date: 08/10/00

Re: Document Number K002321

Memo Regarding Telephone Conversation on 8/09/00

This memo confirms the telephone conversation held at 2:45pm on 8/09/00 between Kathleen Barber of Breg, Inc. and Sarah Foster of DDIGD/GHDB. A request to Ms. Barber was made to remove a statement in the device comparison table stating that the Breg 2000L is applicable to orthopedic surgical procedures. Since the predicate device, the Breg 2000, was not cleared for orthopedic procedures in its indications for use, any implication that the proposed device be used for orthopedic procedures must be deleted. Attached is a copy of the memorandum of the telephone conversation held on November 19, 1998 between Kathleen Barber of Breg, Inc and Irene Naveau and Hung Trinh of DDIGD/GHDB. Ms. Naveau and Mr. Trinh requested Ms. Barber to remove any suggested indications that the Breg 2000 is indicated for use in orthopedic procedures.

Also requested was the material used for the new flow restrict tubing. These items were faxed to DDIGD on 8/10/00 and will be added to the Special 510(k) 002321. A hard copy will follow.

Sarah Foster

2611 Commerce Way
Vista, CA 92083

BY FAX: **301.480.3002**

DATE: **August 10, 2000**

Attn: **Sarah Foster**

RE: **Pain Care 2000L K002321**

Thank you for your telephone call of Wednesday August 9, 2000.

As you requested, I have modified and attached the following document:

- Page 8: The table has been modified to remove the reference to orthopedic procedures.

If you have any questions which may be appropriately answered by phone, then please telephone my office at (760) 599-5719, during the hours of 8:30AM - 5:00PM, PST. Thank you for your attention to this document.

Sincerely yours,

Kathleen Barber
Vice President of Regulatory Affairs

Comparison of Features Pain Care 2000L v. Pain Care 2000

Device Name	Pain Care 2000L	Pain Care 2000
Manufacturer	BREG, Inc.	BREG, Inc.
Type	Patient Controlled, Spring Loading Syringe Injected, Single Patient Use	Patient Controlled, Spring Loading Syringe Injected, Single Patient Use
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Duration	2-3 Days	2-3 Days
Applications	Procedures requiring local analgesic non-narcotic pain relief.	Procedures requiring local analgesic non-narcotic pain relief.
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2611 Commerce Way
Vista, CA 92083

BY FAX: 301.480.3002

DATE: August 10, 2000

Attn: Sarah Foster

RE: Pain Care 2000L K002321

Thank you for your telephone call of Wednesday August 9, 2000.

As you requested, I have modified and attached the following document:

- Page 9: The material for the flow restrictor tubing and catheter is polyurethane. This has been added to the drawing.

If you have any questions which may be appropriately answered by phone, then please telephone my office at (760) 599-5719, during the hours of 8:30AM - 5:00PM, PST. Thank you for your attention to this document.

Sincerely yours,

Kathleen Barber
Vice President of Regulatory Affairs

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DATE: November 19, 1998

MEMORANDUM OF TELEPHONE CONVERSATION

Between: Irene Naveau, Nurse Consultant
DDIG/GHDB, HFZ-480

Hung Trinh, Biomedical Engineer
DDIGD.GHDB, HFZ-480

And: Ms. Kathleen Barber
Vice President
QA/RA
Breg, Inc.

Hung and I initiated a telephone conversation with Ms. Barber to discuss, primarily, the indication for use for the Pain Care 2000 infusion pump. We explained to her that we had been clearing this type of pump for general surgical use. Ms. Barber's comparison table indicated that the indications for the Pain Care 2000 were similar to the indications for I-Flow Corporation's PainBuster, K980558. We have, however, not cleared the PainBuster for orthopedic surgical procedures, therefore, we suggested that the indications for orthopedic procedures be removed from the Indications for Use Statement. We also suggested that any reference to intra-articular and orthopedic procedures be deleted from this document. She agreed to do this.

The labeling included an international icon for single use, however we suggested that a statement, For Single Use Only, be included in the label.

There is some confusion regarding the amount of solution/medication which would be infused with each dose. The label on page 11, Attachment #1, states that there is 4ml volume per dose, while the label on page 13 states: 3ml (max) per hour. Again, there are statements, on page 17 in the questions and answers format that refer to 3ml as the volume. We suggested that this be clarified and that volume amounts be consistent in the label and on the device itself.

Page 4 of Amendment #1 states that the flow control permits filling of the spring loading syringe at a rate not to exceed 16cc per hour; Page 17 includes an answer statement that the syringe fills at a rate not to exceed 3cc per hour. We asked that she clarify these statements.

Ms. Barber was in agreement with our suggestions, and will forward the additional information.

Irene Naveau

Irene Naveau

Screening Checklist
For all Premarket Notification 510(k) Submissions

Device Name: Pain Care 2ml L | **K** 002321

Submitter (Company): Baxa, Inc.

Items which should be included *(circle missing & needed information)*	SPECIAL YES	SPECIAL NO	ABBREVIATED YES	ABBREVIATED NO	TRADITIONAL YES	TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
1. Cover Letter clearly identifies Submission as:							
a) "Special 510(k): Device Modification"	✓ GO TO # 2,3						
b) "Abbreviated 510(k)"			GO TO # 2,4,5				
c) Traditional 510(k)					GO TO #2 4,5		

2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS	NA SPECIALS YES	NA SPECIALS NO	YES ABBREVIATED YES	YES ABBREVIATED NO	NO TRADITIONAL YES	NO TRADITIONAL NO	✓ IF ITEM IS NEEDED AND IS MISSING
Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i)							
a) trade name, classification name, establishment registration number, device class							
b) OR a statement that the device is not yet classified	FDA-may be a classification request; see coordinator						
c) identification of legally marketed equivalent device	NA						
d) compliance with Section 514 - performance standards	NA						
e) address of manufacturer							
f) Truthful and Accurate Statement							
g) Indications for Use enclosure							
h) SMDA Summary or Statement *(FOR ALL DEVICE CLASSES)*							
i) Class III Certification & Summary *(FOR ALL CLASS III DEVICES)*							
j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals							
k) Proposed Labeling:							
i) package labeling (user info)							
ii) statement of intended use							
iii) advertisements or promotional materials							
i) MRI compatibility (if claimed)							
l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include:							
i) Labeling							
ii) intended use							
iii) physical characteristics							
iv) anatomical sites of use							
v) performance (bench, animal, clinical) testing	NA						
vi) safety characteristics	NA						
m) If kit, kit certification							

3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II , III OR RESERVED CLASS I DEVICE			
a) Name & 510(k) number of legally marketed (unmodified) predicate device			
b) *STATEMENT - INTENDED USE AND INDICATIONS FOR*		* If no - STOP not a special	

*USE OF MODIFIED DEVICE AS DESCRIBED IN ITS LABELING HAVE NOT CHANGED**				
c) *STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED**			* If no - STOP not a special	
d) Design Control Activities Summary				
i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis				
ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied				
iii) A declaration of conformity with design controls. The declaration of conformity should include:				
1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met				
2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review.				

	SPECIALS		ABBREVIATED		TRADITIONAL		✓ IF ITEM IS NEEDED AND IS MISSING
	YES	NO	YES	NO	YES	NO	
4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE							
a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type							
b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach.							
c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following:							
i) An identification of the applicable recognized consensus standards that were met							
ii) A specification, for each consensus standard, that all requirements were met, except for							

inapplicable requirements or deviations noted below						
iii) An identification, for each consensus standard, of any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed						
iv) An identification, for each consensus standard, of any requirements that were not applicable to the device						
v) A specification of any deviations from each applicable standard that were applied						
vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference						
vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations						
d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards						

5. Additional Considerations: (may be covered by Design Controls)							
a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation:							
i) component & material							
ii) identify patient-contacting materials							
iii) biocompatibility of final sterilized product							
b) Sterilization and expiration dating information:							
i) sterilization method							
ii) SAL							
iii) packaging							
iv) specify pyrogen free							
v) ETO residues							
vi) radiation dose							
c) Software validation & verification:							
i) hazard analysis							
ii) level of concern							
iii) development documentation							
iv) certification							

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening ✓ Yes ____ No
Date: 8/11/00

Reviewer: Sarah Foster
Concurrence by Review Branch: ____

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K 002321

Reviewer: Sarah Foster

Division/Branch: DD1GD/GHDB

Device Name: Breg Pain Care 3000L

Product To Which Compared (510(K) Number If Known): K983454

	YES	NO	
1. Is Product A Device	✓		If NO = Stop
2. Is Device Subject To 510(k)?	✓		If NO = Stop
3. Same Indication Statement?	✓		If YES = Go To 5
4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?			If YES = Stop NE
5. Same Technological Characteristics?	✓		If YES = Go To 7
6. Could The New Characteristics Affect Safety Or Effectiveness?			If YES = Go To 8
7. Descriptive Characteristics Precise Enough?	✓		If NO = Go To 10 If YES = Stop SE
8. New Types Of Safety Or Effectiveness Questions?			If YES = Stop NE
9. Accepted Scientific Methods Exist?			If NO = Stop NE
10. Performance Data Available?			If NO = Request Data
11. Data Demonstrate Equivalence?			Final Decision:

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:

2. Explain why not subject to 510(k):

3. How does the new indication differ from the predicate device's indication:

4. Explain why there is or is not a new effect or safety or effectiveness issue:

5. Describe the new technological characteristics:

6. Explain how new characteristics could or could not affect safety or effectiveness:

7. Explain how descriptive characteristics are not precise enough:

8. Explain new types of safety or effectiveness questions raised or why the questions are not new:

9. Explain why existing scientific methods can not be used:

10. Explain what performance data is needed:

11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

	YES	NO
1. Did the firm request expedited review? 2. Did we grant expedited review?		
3. Have you verified that the Document is labeled Class III for GMP purposes? 4. If, not, has POS been notified?		
5. Is the product a device? 6. Is the device exempt from 510(k) by regulation or policy? 7. Is the device subject to review by CDRH?		
8. Are you aware that this device has been the subject of a previous NSE decision? 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)?		
10. Are you aware of the submitter being the subject of an integrity investigation? 11. If, yes, consult the ODE Integrity Officer. 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991.		

DEPARTMENT OF HEALTH AND HUMAN SERVICES — Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

July 31, 2000

BREG, INC.
2611 COMMERCE WAY
VISTA, CA 92083
ATTN: KATHLEEN BARBER

510(k) Number: K002321
Received: 31-JUL-2000
Product: PAIN CARE 2000L

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

On January 1, 1996, FDA began requiring that all 510(k) submitters provide on a separate page and clearly marked "Indication For Use" the indication for use of their device. If you have not included this information on a separate page in your submission, please complete the attached and amend your 510(k) as soon as possible. Also if you have not included your 510(k) Summary or 510(k) Statement, or your Truthful and Accurate Statement, please do so as soon as possible. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers Assistance (DSMA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the Document Mail Center will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the Document Mail Center (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address http://www.fda.gov/cdrh/dsmamain.html or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Consumer Safety Officer
Premarket Notification Staff
Office of Device Evaluation
Center for Devices and Radiological Health

K002321

BREG

2611 Commerce Way
Vista, CA 92083

BY PRIORITY MAIL

July 28, 2000

Document Mail Center(HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850

Attn.: Document Clerk

I am the representative of Breg, Inc., Vista, CA. As required by section 510(k) of the FDC Act, 1976 and the Safe Medical Devices Act of 1990, I hereby submit a **Special 510(k) Premarket Notification** (enclosed) to indicate the intention of Breg, Inc. to manufacture and introduce into commercial distribution a medical device named the **PAIN CARE 2000L**. The information required by 21 CFR807.87 is included in the enclosed 510(k) notification.

I believe this submission is subject to review and approval of the ODE, Division of Dental, Infection Control and General Hospital Devices.

Please direct all correspondence regarding this submission to me at the letterhead address. If you have any questions which may be appropriately answered by phone, then please telephone my office at (760) 599-5719, during the hours of 8:30AM - 5:00PM, PST. Thank you for your attention to this document.

Sincerely yours,

Kathleen Barber
Vice President of Regulatory Affairs

Enclosures: 2 copies of 510(k) with cover letter attached

FDA/CDRH/ODE/DDC
31 JUL 00 13 37
RECEIVED

SPECIAL 510(k): Device Modification

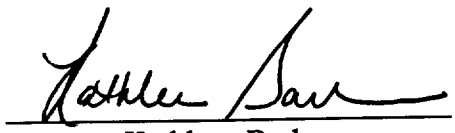
for the

PAIN CARE 2000L

Manufactured by

BREG, INC.
2611 Commerce Way
Vista, CA 92083
Tel: (760) 599-3000
Fax (760) 598-6193

Document submitted by the official correspondent of
BREG, Inc.



Kathleen Barber
Vice President of Regulatory Affairs
BREG, Inc.

28 July, 2000

31 JUL 00 13:39
FDA/CDRH/ODE/DMC

TABLE OF CONTENTS

1. MANUFACTURER/FDA REGISTRATION

The manufacturer of the device is:

BREG, Inc.
2611 Commerce Way
Vista, CA 92083-8309
Tel: (760) 599-3000
Fax: (760) 598-6193

The FDA Registration Number is 2028253. Contract Sterilization will be provided by (b)(4) whose FDA Registration Number is (b)(4)

2. DEVICE NAME

The proprietary name of the product is **PAIN CARE 2000L**. It is a modification to the BREG, Inc. product, **PAIN CARE 2000, K983454.**

3. DEVICE DESCRIPTION

BREG's Pain Care 2000L consists of a dispensing device that is connected via a Luer LOK connector to a standard 16 gauge epidural catheter. Included is a standard 16 gauge intravenous (IV) catheter insertion needle to assist in insertion of the standard 16 gauge epidural catheter into the operative site. A 60 cc syringe is also supplied to aid in filling the dispensing device with fluid (appropriate local anesthetic recommended by a licensed physician).

The dispensing device consists of fluid reservoir bag (approximately 50 cc), a spring loading 5 cc syringe, a flow control, an in-line particulate filter, a section of flow control tubing and two valves. All internal dispensing device components are connected via Luer fittings and then housed in a plastic case. It is made up of the same components with the addition of the flow control tubing and an 'L' fitting.

The plastic case has an exterior button enabling the user to depress the spring loading syringe, and thus injecting the fluid that has accumulated in the spring loading syringe through the catheter and into the operative site. The flow control tubing is between the fluid reservoir and the spring loading 5 cc syringe. The flow control permits filling of the of the spring loading syringe at a rate, not to exceed, 12 cc per hour. A one way valve is located between the standard 16 gauge epidural catheter and the spring loading 5 cc syringe. The one way valve prevents aspiration of fluids from the standard 16 gauge epidural catheter to the dispensing device . The in-line particulate filter is in-between the fluid reservoir bag and the flow control tubing and thus prevents clogging of the flow control.

There is a second one way Luer LOK fill port on the exterior of the case that is connected to the 50 cc fluid reservoir bag inside the case. This port permits injection of the fluid via the 60 cc syringe . The fill port also has a tethered removable cap to maintain sterility

and to ensure that the proper pressure is maintained within the fluid reservoir and system. There is an outflow port that connects the dispensing device to the standard 16 gauge catheter. Fluid that has accumulated within the spring loading 5 cc syringe is injected through this port to the catheter and into the operative site by depressing the button on the case. (See Diagram 1 for complete configuration) The patient is able to dispense local anesthetic into the operative site for pain relief. The design of the Pain Care 2000L permits administration of local anesthetic at a rate not to exceed 12 cc per hour. All components are provided in a sterile package.

MECHANICAL FUNCTION

- Fluid reservoir bag filled with fluid through the fill port.
- Fill port capped.
- Button is depressed (which depresses the spring loading 5 cc syringe) to prime system.
- Standard 16 gauge epidural catheter is connected to outflow port via Luer fitting.
- Spring loading 5 cc syringe creates an aspirating vacuum within the system (The spring that is attached to the syringe continually draws out the plunger of the syringe until maximum capacity is reached).
- Fluid from the fluid reservoir bag is aspirated through particulate filter .
- Fluid that passes through the particulate filter passes through the flow control tubing and into the 5 cc spring loading syringe.
- The one way valve between 5 cc spring loading syringe and catheter prevents aspiration of fluids from the standard 16 gauge epidural catheter back to the syringe.
- As determined by the user's pain need, the button on the case is depressed.
- Plunger of 5 cc spring loading syringe is depressed via button.
- Fluid is injected through the one way valve, through the out port, through the catheter, and into the operative site.
- Flow control prevents injection of fluid back into the fluid reservoir.
- Cycle repeats.
- Patient depresses button as need for pain.
- Pain Care 2000L use is discontinued once fluid reservoir is empty
- The Pain Care 2000L will last for approximately 2-3 days of use, depending upon local analgesia duration prior to the next injection.
- Catheter is removed by day three.

SUMMARY OF DESIGN CONTROL ACTIVITIES

- **Risk Analysis**

Risk analysis was performed using FMEA to identify those areas which posed the greatest failure risk in the manufacture of the Pain Care 2000L. Each issue was assigned a value and actions were assigned to eliminate or reduce the risk to a level that had no effect on the safety or efficacy of the product. The results of this analysis are availabe for review in the BREG, Inc. Engineering department.

- **Validation/Verification**

Validation and verification was performed based upon the intended design outputs of the device from the Product Development Specifcation as well as upon the assurance that any areas of great risk identified by the risk analysis were corrected.

Specific examples of items that were validated include:

1. **The material of the flow control tubing was determined to be of the same composition as that of the Pain Care 2000 catheter, the biocompatibility results meet the AAMI, and ISO requirements.**
2. **The sterilization process was validated for the Pain Care 2000L using AAMI, ISO and GLP standards.**
3. **The flow rate was tested with the flow control tubing at different to verify that the rate did not exceed 12ml/hour. These tests included variances in tube length and ID for full spectrum results.**
4. **The spring back force on the button was validated for consistent pressure.**
5. **Heat Accelerated Life Testing was performed on assemblies to determine the shelf life**
6. **The assembly process was validated**
7. **Testing was performed on units to determine if the testing equipment was valid to include both alpha and beta failure modes.**

DECLARATION OF CONFORMITY

1. **As required by risk analysis, all verification and validation activities for the Pain Care 2000L were performed by the BREG, Inc. Engineering staff. The results demonstrate that the predetermined acceptance criteria were met.**

2. **BREG, Inc. is a FDA registered manufacturing facility and is in compliance with all the design control procedure requirements as specified in 21 CFR 820.30 and the results are available for review.**

Kathleen Barber 7/28/2000

Kathleen Barber
Vice President, RA/QA

STERILITY ASSURANCE:

The type of sterilization i(b)(4) gamma radiation performed by (b)(4)
(b)(4) o acheive a sterility assurance level of 10 to the -6. This process is equivalent to the Pain Care 2000 device

The sterility validation methodology used to initially establish our dose requirements and our ongoing quarterly audits complies with the following specifications: (1) USP Section 71; (2) ISO-11135; and (3) ANSI/AAMI Method 1.

Parts will be packed into industry recognized sterilazation pouches designed for radiation applications which are heat sealed prior to sterilization.

STATEMENT OF INDICATIONS FOR USE

Intended Use

BREG's Pain Care 2000L is intended to provide patient controlled intermittent infusion of a local anesthetic into an intra-operative site for the post-operative management of pain.

The purpose of BREG's Pain Care 2000L is to provide a delivery mechanism of local anesthetic maintenance doses in order to sustain pain relief that is initially established by the bolus of local anesthetic that is injected intra-operatively (loading dose).

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002321

Device Name	Manu-facturer	Type	Capacity	Rate	Duration	Applicati
Pain Care 2000	Breg, Inc.	Patient Controlled, Spring Loading Syringe Injected, Flow Restrictor for Syringe Filling, Single Patient Use	50 cc	4 cc per Injection	2-3 Days	Orthopedi cedures re local analg non-narcot pain relief.
Pain Care 2000L	Breg, Inc.	Patient Controlled, Spring Loading Syringe Injected, Flow Restrict tubing for Syringe Filling, Single Patient Use	50 cc	4 cc per Injection, no more than 12cc per hour	2-3 Days	Orthopedic cedures req local analg non-narcoti pain relief.

(b)(4)

#	DESCRIPTION	MATE
1	(b)(4)	
2		
3		
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11		
12		
13		
14		
15		
16		

(b)(4)

PACKAGE LABELING

PMS: 327

BREG™

Breg, Inc., 2611 Commerce Way, Vista, CA 92083 U.S.A.

PART NO. 10323
CONTENTS / INHALT / CONTENU / CONTENIDO: 1

PAIN CARE™ 2000L

Patient Controlled Local Anesthetic Infusion Device

50 ml Volume • 4 ml Volume per Dose • Flow Rate: < 12 ml per Hour

For Single Patient Use Only

Contents of Unopened, Undamaged Package are:

STERILE R

CONTENTS:
1 each - 50 ml Vol., 4 ml Infusion Device
1 each - Catheter Introducer Needle
1 each - 16 GA Catheter Set
1 each - Tube Extension Set
1 each - 60 cc Latex Free Syringe

SEE DIRECTIONS FOR USE. CAUTION: FEDERAL LAW (U.S.A.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A HEALTHCARE PROFESSIONAL

E/U Authorized Representative
MDSS
Burckhardtstrasse 1
D-30163 Hanover
Germany

PATENTS PENDING

P/N 1.09030 Rev. A 4/00

To Reorder Call:
(800) 321-0607
(760) 599-3000

CE 0086

USE INSTRUCTIONS

PAIN CARE™ 2000L

DIRECTIONS

ANLEITUNG FÜR DAS *PAIN CARE™ 2000L*–SYSTEM

ISTRUZIONI PER L'USO DEL DISPOSITIVO *PAIN CARE™ 2000L*

MODE D'EMPLOI DU *PAIN CARE™ 2000L*

INSTRUCCIONES PARA EL *PAIN CARE™ 2000L*

Patents Pending

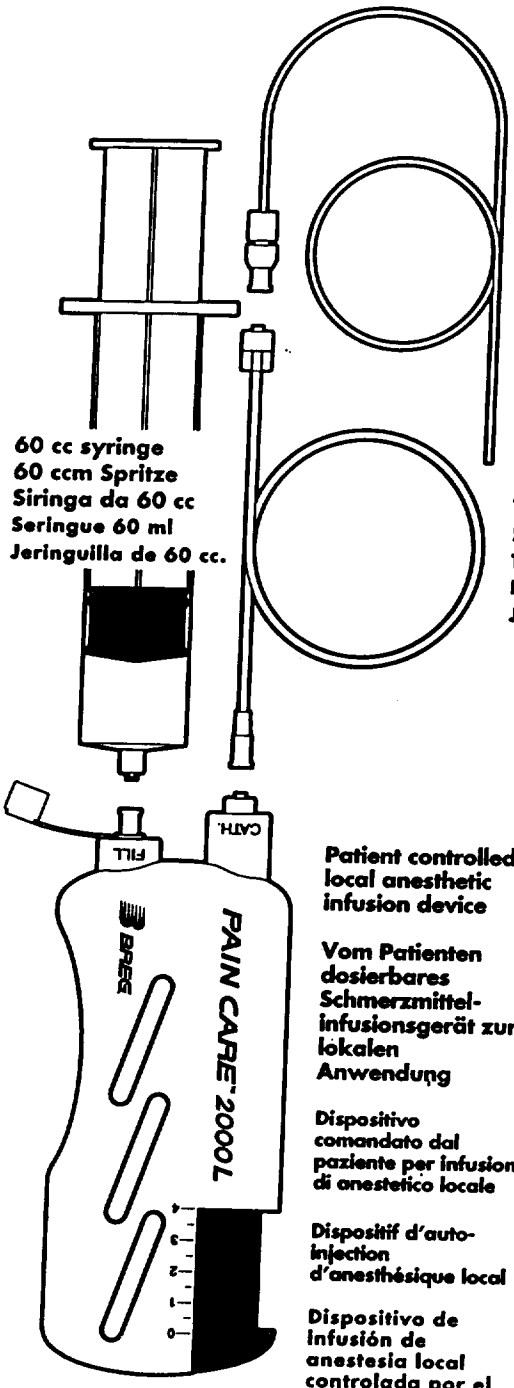
CE 0086

E/U authorized representative
MOSS
Berckhardtstrasse 1
D-30163 Hanover
Germany

BREG Inc.
2611 Commerce Way
Vista, CA 92083 U.S.A.

Telephone (800) 321-0607
(760) 599-3000
Telefax (760) 598-6193

PN-1.09220 REV A 6/00



Catheter
Katheter
Catetere
Cathéter
Catéter

60 cc syringe
60 ccm Spritze
Siringa da 60 cc
Seringue 60 ml
Jeringuilla de 60 cc.

Tube extension set
Schlauchverlängerungssatz
Tubo di prolunga
Rallonge de tubulure
Juego de extensión del tubo

Patient controlled local anesthetic infusion device

Vom Patienten dosierbares Schmerzmittel-infusionsgerät zur lokalen Anwendung

Dispositivo comandato dal paziente per infusione di anestetico locale

Dispositif d'auto-injection d'anesthésique local

Dispositivo de infusión de anestesia local controlada por el paciente

⚠ CAUTION

FEDERAL (U. S. A.) LAW RESTRICTS THIS DEVICE TO BE SOLD BY THE ORDER OF A HEALTH CARE PROFESSIONAL.

⚠ ACHTUNG

PER GESETZ DARF DIESES GERÄT NUR AUF ANWEISUNG EINER MEDIZINISCH AUSGEBILDETEN PERSON VERKAUFT WERDEN.

⚠ ATTENZIONE

LE LEGGI FEDERALI DEGLI STATI UNITI VIETANO LA VENDITA DI QUESTO DISPOSITIVO A PERSONALE NON AUTORIZZATO O SENZA PRESCRIZIONE MEDICA.

⚠ ATTENTION

LA LEGISLATION FEDERALE AMERICAINE AUTORISE LA VENTE DE CE DISPOSITIF UNIQUEMENT SUR ORDONNANCE D'UN SPECIALISTE MEDICAL.

⚠ PRECAUCIÓN

LA LEY FEDERAL (EE.UU.) RESTRINGE LA VENTA DE ESTE DISPOSITIVO A CASOS DE RECOMENDACIÓN POR PARTE DE UN PROFESIONAL MÉDICO.

INTENDED USE

BREG's *Pain Care™ 2000L* is intended to provide patient controlled intermittent infusion of a local anesthetic into an operative site for the postoperative management of pain. Maximum dose rate not to exceed 12 ml per hour.

DIRECTIONS FOR USE

Use Aseptic Technique at All Times

Filling the Fluid Reservoir Bag of *PAIN CARE™ 2000L*

1. Fill the 60 cc syringe with 50 cc of local anesthetic (e.g. 0.25% bupivacaine) as prescribed by the patient's physician.
2. Remove the protective cap from the FILL port.
3. Attach the 60 cc syringe via the Luer fitting to this port.
4. Inject 50 cc of the local anesthetic into the fluid reservoir through the FILL port. (Do Not Overfill.)
5. Reapply the protective cap to the FILL port.

PLACING THE CATHETER

1. Insert the catheter introducer needle through the skin (approximately 3-5 cm away from wound site). Push the catheter introducer needle into the surgical site.
2. Remove the introducer needle from the insertion catheter.
3. Insert the marked end of the 16 gauge catheter through the center of the insertion catheter and into the wound site.
4. Remove the insertion catheter while holding the 16 gauge catheter tightly in place.
5. Secure the catheter placement in the wound site by taping in place.
6. Strain relieve the catheter by looping it back on itself and taping it down again.
7. Insert the free end of the catheter through the small hole of the catheter connector cap. Completely push the catheter into the connector until the catheter marking is not visible. Tighten the catheter connector onto the catheter by twisting the cap firmly into place.
8. Attach the tube extension set to the catheter connector via the Luer fitting.
9. Connect a syringe filled with the appropriate local anesthetic loading dose to the Luer fitting of the tube extension set. Inject the loading dose of the anesthetic into the wound site by infiltrating through the catheter.
10. Apply the appropriate dressing to the catheter insertion site.

ATTACHING CATHETER TO *PAIN CARE™ 2000L*

1. Attach the Luer LOK fitting of the tube extension set to the port labeled CATH by twisting until secure.

ATTACHING OPTIONAL "Y" ACCESSORY KIT (FOR INFUSION OF TWO SITES)

1. Place the additional catheter provided in the "Y" Kit in the second wound site as described above.
2. Connect the "Y" connector to each of the catheter connectors via the Luer fittings by twisting until secure.
3. Connect the free end of the "Y" connector to the end of the tube extension set.

STARTING THE *PAIN CARE™ 2000L*

1. Ensure all connections and caps are secure.
2. Secure the *Pain Care™ 2000L* via metal clip to the outer dressing, waistband, belt, clothing, or brace/sling.
3. Depress the Blue Button per the physician's orders as needed for pain. Depressing the Blue Button injects the local anesthetic through the catheter and into the wound site.

DISCONTINUING THE USE OF *PAIN CARE™ 2000L*

1. Infusion is complete when the *Pain Care™ 2000L* is empty. (When the fluid reservoir is empty.)
2. The catheter should be removed at this time unless a refill is prescribed by your physician.
3. For catheter removal, consult a licensed health care provider.

WARNINGS

1. The *Pain Care™ 2000L* is designed to be applied by a licensed health care provider.
2. All medication used in the *Pain Care™ 2000L* is to be prescribed by a licensed physician.
3. The entire contents of this device (50 cc) may be dispensed in 12-13 successive doses (within approximately 4 hours). For safe use of the device, it is essential that the choice of medications be carefully determined for each patient.
4. Patient education regarding proper use must be initiated by a licensed health care provider.
5. Use sterile technique at all times during implantation of the catheter, while completing all connections to the *Pain Care™ 2000L* with the local anesthetic, and upon removal of the catheter from the insertion site upon completion. If sterile technique is violated, a possible risk of infection exists.
6. Disposal – Single patient use only.
7. Discard/destroy after use.
8. Only refill the device in accordance with physician's instructions.
9. Do not re-sterilize any of the components of the *Pain Care™ 2000L*.
10. Do not overfill the fluid reservoir bag.
11. Medications being used with the *Pain Care™ 2000L* should be used in accordance with the instructions provided from the drug manufacturer.
12. Consult the drug manufacturer's recommendation for maximum safe single dose limitation.
13. If any of the Luer LOK catheter connections becomes disconnected from the *Pain Care™ 2000L* or if the catheter becomes disconnected from the Luer LOK catheter connector AFTER the surgical procedure is completed, do NOT reconnect it. A licensed health care provider must be contacted for catheter removal.
14. Avoid dropping the *Pain Care™ 2000L*. If the *Pain Care™ 2000L* should fall and break, contact the physician.
15. Patients with known allergies or complications arising from the medication used in the *Pain Care™ 2000L* should NOT use the *Pain Care™ 2000L*. The physician must be contacted immediately if any adverse reactions occur such as breathing difficulty, heart rate fluctuations, rash, hives, excessive sweating, or nausea.

PREMARKET NOTIFICATION

TRUTHFUL AND ACCURATE STATEMENT

I certify that, in my capacity as Vice President of Quality Assurance and Regulatory Affairs of BREG, Inc., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

Signature

Kathleen Barber 7/28/2000

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