May 12, 2023

Young-A Kim, Ph.D.
Director, RA/QA
Princeton BioMeditech Corp.
4242 US Hwy 1
Monmouth Junction, NJ 08852

Re: EUA210015/S007
Trade/Device Name: Status COVID-19/Flu A&B
Dated: November 11, 2022
Received: November 11, 2022

Dear Dr. Kim:

This is to notify you that your request is granted to update the authorized labeling of the Status COVID-19/Flu A&B; (1) in response to Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022 to revise the authorized use(s) as required and described in Appendix A, and make various updates to the authorized labeling as required and described in Appendix B of the letter, (2) to relabel the Control Line on the test device cassette from "C" to "Ctrl," and (3) to include results from your ongoing study to further evaluate the clinical performance of the Status COVID-19/Flu A&B in anterior nasal swab specimens for influenza A and B. Upon review, we concur that the information submitted in EUA210015/S007 supports the requested updates for use with the Status COVID-19/Flu A&B and fulfills Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022. The Fact Sheet for Healthcare Providers (HCPs) and Fact Sheet for Patients have been updated by FDA consistent with this revision and are included along with this letter.

By submitting this supplemental request for review by the Food and Drug Administration (FDA), you have complied with and fulfilled Condition of Authorization (1) of the Repeat Testing Revision Letter dated November 1, 2022, and complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the Status COVID-19/Flu A&B issued on October 27, 2021.

Sincerely yours,

_____

Uwe Scherf, M.Sc., Ph.D.
Director, Division of Microbiology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health