U.S. FOOD & DRUG ADMINISTRATION

January 30, 2019

Tiffany Miller,
Director Regulatory Affairs
OraSure Technologies, Inc.
220 East First Street
Bethlehem, PA 18015 US

Re: EUA150006/A002
Trade/Device Name: OraQuick Ebola Rapid Antigen Test For Use With Whole Blood
Dated: September 26, 2018
Received: September 27, 2018

Dear Mrs. Miller:

This is to notify you that your request to modify the Instructions for Use of the OraQuick Ebola Rapid Antigen Test for use with Whole Blood to include new data on (1) Clinical Performance, (2) Interference, (3) Cross Reactivity and (4) reproducibility of the device and to modify minor wording in the intended use of the device has been granted.

Upon review, we concur that the data submitted in EUA150006/A002 supports the addition of the afore mentioned data to the Instructions for Use. By submitting this amendment for review by the Food and Drug Administration (FDA), you have complied with the Conditions of Authorization stated in the letter authorizing the emergency use of the OraQuick Ebola Rapid Antigen Test issued on July 31, 2015.

Sincerely yours,

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