March 19, 2018

Longhorn Vaccines and Diagnostics LLC
Jeff Fischer
Chief Financial Officer
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Bethesda, Maryland 20814

Re: DEN170029
Trade/Device Name: PrimeStore MTM
Regulation Number: 21 CFR 866.2950
Regulation Name: Microbial nucleic acid storage and stabilization device
Regulatory Class: Class II
Product Code: QBD
Dated: May 23, 2017
Received: May 25, 2017

Dear Jeff Fischer:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the PrimeStore MTM, a prescription device with the following indications for use:

> PrimeStore MTM is intended for the stabilization, transportation and inactivation of infectious unprocessed nasal washes suspected of containing Influenza A virus RNA. PrimeStore MTM is also intended for the stabilization, transportation and inactivation of infectious unprocessed sputum samples suspected of containing Mycobacterium tuberculosis DNA from human samples.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the PrimeStore MTM, and substantially equivalent devices of this generic type, into Class II under the generic name microbial nucleic acid storage and stabilization device.

FDA identifies this generic type of device as: **Microbial nucleic acid storage and stabilization device**.

> A microbial nucleic acid storage and stabilization device is a device that consists of a container and reagents intended to stabilize microbial nucleic acids in human specimens for subsequent isolation and purification of nucleic acids for further molecular testing. The device in not intended for preserving morphology or viability of microorganisms.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This new law provides two options for De Novo classification. First, any person who receives a "not substantially

equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register classifying the device type.

On May 25, 2017, FDA received your De Novo requesting classification of the PrimeStore MTM. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the PrimeStore MTM into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the PrimeStore MTM can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks to Health	**Mitigation Measures**
Failure to stabilize pathogen nucleic acid resulting in a false negative result	General Controls and Special Controls (1), (2), and (3)
Failure to inactivate the specimen	General Controls and Special Controls (1), (2)(i), (2)(ii), (3)(i), (3)(ii) and (3)(iv)

In combination with the general controls of the FD&C Act, the microbial nucleic acid storage and stabilization device is subject to the following special controls:

(1) The intended use for the 21 CFR 809.10 labeling must include a detailed description of microorganisms and types of human specimens intended to be preserved.

(2) The 21 CFR 809.10(b) labeling must include:

(i) A detailed device description, including all device components.

(ii) Performance characteristics from applicable analytical studies, including but not limited to, nucleic acid stability and microorganism inactivation.

(iii) A limiting statement that erroneous results may occur when the transport device is not compatible with molecular testing.

(iv) A limiting statement that the device has only been validated to preserve the representative microorganisms used in the analytical studies.

(3) Design verification and validation must include the following:

(i) Overall device design including all device components and all control elements incorporated into the analytical validation procedures.

(ii) Thorough description of the microorganisms and methodology used in the validation of the device including, but not limited to, extraction platforms and assays used for the detection of preserved nucleic acids.

(iii) The limit of detection (LoD) of the molecular test used to establish microorganism nucleic acid stability.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the microbial nucleic acid storage and stabilization device they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website

(http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

If you have any questions concerning the contents of the letter, please contact David Goodwin at 301-796-6932.

Sincerely,

Kristian M. Roth -S For:

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