SUPPLEMENT APPROVAL
May 25, 2018

Our STN: BL 125121/80

Grifols Diagnostic Solutions, Inc.
Attention: Ms. Amanda Doe
10210 Genetic Center Drive
San Diego, CA 92121-4362

Dear Ms. Doe:

We have approved your request dated June 29, 2016, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for West Nile Virus (WNV/Nucleic Acid Pooled Testing/Synthetic) for a new automated Procleix Panther System platform to be used with the licensed Procleix WNV Assay. The assay is to be manufactured at your facilities located in (b) (4) and run on the Procleix Panther System manufactured by (b) (4)

LABELING

We hereby approve the draft package insert labeling submitted under amendment #12, dated February 22, 2018, and the draft carton and container labeling submitted under amendment #8, dated November 28, 2017. This is a reminder that as of September 24, 2014, medical devices that are licensed under the PHS Act are subject to certain provisions of the final Unique Device Identifier (UDI) rule. These provisions include the requirement to provide a UDI on the device label and packages (21 CFR 801.20), format dates on the device label in accordance with 21 CFR 801.18, and submit data to the Global Unique Device Identification Database (GUDID) (21 CFR 830 Subpart E). Additionally, please identify each device identifier implemented for the subject device, and the device identifiers that have been discontinued for the subject device as a labeling change in an annual report consistent with 21 CFR 601.12(f)(3). For more information on these requirements, please see the UDI website, http://www.fda.gov/udi.

Please submit all final printed labeling as PDF electronic copy (eCopy) at the time of use and include implementation information on Form FDA 356h as appropriate.

Two draft copies of the proposed introductory advertising or promotional labeling may be voluntarily submitted for advisory comment with a completed Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

We will include the information contained in the above-referenced supplement in your BLA file.

Sincerely,

Hira L. Nakhasi, PhD
Director
Division of Emerging and Transfusion
Transmitted Diseases
Office of Blood Research and Review
Center for Biologics Evaluation and Research