DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 1, 2017

HARDY DIAGNOSTICS
RIANNA MALHERBE
LEAD PERFORMANCE STUDIES MICROBIOLOGIST
1430 WEST MCCOY LANE
SANTA MARIA CA 93455

Re: K171975
Trade/Device Name: HardyDisk AST Delafloxacin 5 µg (DLX5)
Regulation Number: 21 CFR 866.1620
Regulation Name: Antimicrobial susceptibility test disc
Regulatory Class: II
Product Code: JTN
Dated: June 29, 2017
Received: June 30, 2017

Dear Ms. Malherbe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ribhi Shawar -S For

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171975

Device Name
HardyDisk™ AST Delafloxacin 5µg (DLX5)

Indications for Use *(Describe)*
Use of HardyDisk™ AST Delafloxacin 5µg (DLX5) , for *in vitro* agar diffusion susceptibility testing is indicated when there is need to determine the susceptibility of bacteria to Delafloxacin.

The concentration of Delafloxacin 5µg (DLX5), has been shown to be active against susceptible isolates of the following microorganisms both *in vitro* and in clinical infections:
Staphylococcus aureus (including methicillin-resistant and methicillin-sensitive strains)
Staphylococcus haemolyticus
Streptococcus pyogenes
Streptococcus anginosus Group (including *S. anginosus, S. intermedius, S. constellatus*)
Enterococcus faecalis
Escherichia coli
Klebsiella pneumoniae
Enterobacter cloacae
Pseudomonas aeruginosa

The concentration of Delafloxacin 5µg (DLX5), has been shown to be active against susceptible isolates of the following microorganisms for *in vitro* use:
Streptococcus dysgalactiae
Enterobacter aerogenes
Haemophilus parainfluenzae
Klebsiella oxytoca
Proteus mirabilis

HardyDisk™ AST Disks are used for semi-quantitative *in vitro* susceptibility testing by the agar diffusion test procedure (Kirby-Bauer) of rapidly growing and certain fastidious bacterial pathogens. Standardized methods for agar diffusion testing have been described for *Enterobacteriaceae, Staphylococcus* spp., *Pseudomonas* spp., *Acinetobacter* spp., *Listeria monocytogenes, Enterococcus* spp., and by modified procedures, *Haemophilus* spp., *Neisseria gonorrhoeae, N. meningitidis* and *Streptococcus* spp., including *Streptococcus pneumoniae.*

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."