



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

JAN - 8 2010

Ms. Wendy Phillips
Hardy Diagnostics
1430 McCoy Lane
Santa Maria, CA 93455

Re: K093807

Trade/Device Name: Hardy Disk μ g Telavancin, 30 μ g
Regulation Number: 21 CFR 866.1620
Regulation Name: Antimicrobial Susceptibility Test Disc
Regulatory Class: Class: II
Product Code: JTN
Dated: December 10, 2009
Received: December 11, 2009

Dear Ms. Phillips:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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

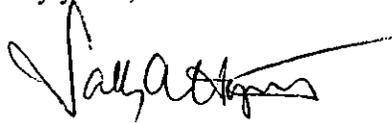
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CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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 Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Sally A. Hojvat, M.Sc., Ph.D.

Director

Division of Microbiology Devices

Office of *In Vitro* Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

Headquarters & Customer Service:1430 West McCoy Lane
Santa Maria, CA 93455phone: (800) 266-2222
fax: (805) 346-2760
email: sales@hardydiagnostics.com
web: www.hardydiagnostics.com**Distribution Centers:**Phoenix, Arizona
Salt Lake City, Utah
Tacoma, Washington
Lima, Ohio

Indications for Use

510(k) Number (if known):

Device Name: HardyDisk Telavancin, 30 µg

Indications for Use:

Use of HardyDisk™ Telavancin 30 µg for *in vitro* agar diffusion susceptibility testing is indicated when there is a need to determine the susceptibility of bacteria to telavancin. The concentration of Telavancin 30 µg has been shown to be active against most isolates of the following microorganisms both *in vitro* and in clinical infections:

Methicillin-resistant staphylococci, streptococci, and vancomycin-susceptible enterococci.

Prescription Use x AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON
ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off**Office of In Vitro Diagnostic Device
Evaluation and Safety**510(k) K093807