



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 23 2006

Mr. Andre Hsiung
Director of Technical Services/R&D
Hardy Diagnostics
1430 W. McCoy Lane
Santa Maria, California 93455

Re: k062245
Trade/Device Name: HardyDisk Tigecycline, 15 µg
Regulation Number: 21 CFR § 866.1620
Regulation Name: Antimicrobial susceptibility test disc
Regulatory Class: II
Product Code: JTN
Dated: July 28, 2006
Received: August 7, 2006

Dear Mr. Hsiung:

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.

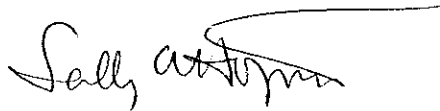
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 CFR Part 807); labeling (21 CFR Parts 801 and 809); 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.

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If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240)276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Sally A. Hojvat", with a long horizontal flourish extending to the right.

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



YOUR MICROBIOLOGY SPECIALIST FOR 25 YEARS AND COUNTING

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1430 West McCoy Lane
Santa Maria, CA 93455

phone: (800) 266-2222
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Distribution Centers:

Phoenix, Arizona
(800) 995-8456

Salt Lake City, Utah
(800) 266-2222

Tacoma, Washington
(800) 266-2222

Lima, Ohio
(800) 266-2222

Indications for Use

510(k) Number (if known): K062245

Device Name: HardyDisk Tigecycline, 15 µg

Indications for Use:

HardyDisktm Tigecycline Antimicrobial Sensitivity Disks are used for semi-quantitative in vitro susceptibility testing by the agar diffusion test procedure (Kirby-Bauer). Zone sizes used for interpretation of tests and control organism limits were determined by the drug manufacturer and received FDA approval under NDA Number 21-821.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(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)

Salazar
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K062245