JAN 1 9 2006

K052323

TREK DIAGNOSTIC SYSTEMS

510(k) SUMMARY

SUBMITTED BY:

TREK Diagnostic Systems
210 Business Park Drive
Sun Prairie, WI 52590

CONTACT NAME:

Nadine M. Sullivan, Ph.D.
Tel. (608) 837-3788 Ext. 152
Fax: (608) 837-3658
Email: nsullivan@trekds.com

DATE PREPARED: August 23, 2005; revised January 17, 2006

DEVICE TRADE NAME: VersaTREK® MYCO PZA KIT

DEVICE COMMON NAME: Antimicrobial susceptibility test powder

DEVICE CLASSIFICATION: 21 CFR 866.1640 - Product code: MJA

PREDICATE DEVICE: BACTEC® 460TB PZA Kit

INTENDED USE:

The VersaTREK® MYCO PZA KIT is used as a rapid qualitative procedure for susceptibility testing of *Mycobacterium tuberculosis*, from culture to pyrazinamide (PZA). The VersaTREK® MYCO PZA KIT is used with the ESP Culture System II (ESP) and the VersaTREK® Microbial Detection System (VTI).

DEVICE DESCRIPTION:

The VersaTREK® MYCO PZA susceptibility testing kit is used with the VersaTREK MYCO culture bottle and performed on the ESP Culture System II and on the VersaTREK® Microbial Detection System. The MYCO bottles are supplemented with Myco Growth Supplement and VersaTREK® MYCO PZA reagent and prepared with the

appropriate dilution of pyrazinamide as the mechanism for performing the susceptibility test.

The VersaTREK® MYCO PZA susceptibility test utilizes a 3 to 15 day testing protocol. A standard suspension of *Mycobacterium tuberculosis* growth is prepared from a liquid (seed inoculum). 0.5 mL is inoculated into a Growth Control bottle (drug-free), and a bottle containing PZA (both bottles are referred to as an AST set). The test determination is based upon growth of the *M. tuberculosis* isolate in the Growth Control Bottle compared to the growth in the drug-containing bottle.

At the completion of the PZA susceptibility testing protocol, the determination of susceptible or resistant is performed manually by the user, by comparing the time to detection of the Growth Control Bottle to the PZA test bottle.

DEVICE COMPARISON

FEATURE	BACTEC 460TB PZA Kit	ESP	VersaTREK
Intended use	Qualitative susceptibility testing of *M. tuberculosis* to pyrazinamide	Same	Same
Test organism	Pure culture of *M. tuberculosis*	Same	Same
Test Drug	PZA	Same	Same
Test determination	Compares growth of a drug-free control to that of PZA	Same	Same
Susceptibility results	Susceptible or resistant	Same	Same
Test protocol cycle	4-21 days	3-15 days	3-15 days
Final PZA Drug concentration/mL	100µg	300µg	300µg
Growth medium	Supplemented Middlebrook H9 with reduced pH	Same	Same
Medium additives	Albumin, catalase	Oleic acid, catalase, dextrose, albumin	Oleic acid, catalase, dextrose, albumin
Inoculum for testing	Subcultured solid or liquid broth	Subcultured liquid (seed) broth	Subcultured liquid (seed) broth
User manipulation for reading	Yes Requires offline incubation	No	No
Sensor	Radioactive labeled carbon dioxide	Pressure sensor	Pressure sensor

	($^{14}CO_2$)-fatty acid		
Monitoring of test	Once daily	Continuous monitoring	Continuous monitoring
Growth monitored by:	Radioactive labeled carbon dioxide ($^{14}CO_2$) liberated into the vial head space	Changes in gas pressure in the bottle head space	Changes in gas pressure in the bottle head space
Interpretation of test	Manually calculated	Same	Same
Organism volume	0.5 mL	0.5 mL	0.5 mL
Incubation Temperature	37°C	35°C	35°C

SUMMARY OF PERFORMANCE DATA:

Analytical studies:

Determination of critical drug concentration:
The determination of critical PZA concentration was done by determining the minimal inhibitory concentration (MIC) for six susceptible wild strains of *Mycobacterium tuberculosis* and four resistant strains. The MIC results of the susceptible strains were ≤200 µg/mL. Thus, the critical concentration was set at 300 µg/mL. Verification of the critical cut off was done with the four resistant strains.

Lot Reproducibility:

Lot reproducibility was performed using 4 well-characterized strains of *Mycobacterium tuberculosis* strains, which were tested in triplicate on three separate days. The strains tested were two ATCC® strains and two strains from CDC. Three different lots of reagents were represented in the testing.. The overall reproducibility was 100% for seeded inoculum.

Two susceptible strains of *M. tuberculosis* were tested at 25, 50, 100 and 200 µg/mL with two lots of Myco broth and GS. The resistant strain, also tested with 2 lots of Myco broth and GS, was tested at 300 µg/mL. There was no difference in results for the susceptible strains, and. all test bottles of the resistant strain were resistant.

Eight lots of manufactured PZA, seven myco broth and six Myco GS were evaluated for reproducibility with acceptable results for all lots.

CDC Challenge Panel Testing

The performance of the VersaTREK® MYCO PZA KIT was evaluated using 10 strains of *Mycobacterium tuberculosis* obtained from the Centers for Disease Control (CDC). Observed results were compared to BACTEC and expected results. The overall agreement was 100 %.

Comparison of the VersaTREK® Microbial Detection System to the ESP Culture System II

Recovery of different microorganisms and the time to detection was used to demonstrate no difference in the performance between ESP Culture System II and the VersaTREK Microbial Detection System with additional testing of *M. tuberculosis* and PZA. There Results and time to detection by either system were not significantly different.

Clinical Studies:

The VersaTREK® MYCO PZA KIT was evaluated at 5 geographical diverse clinical sites, composed of regional reference centers, university- and community-based laboratories.

Lot Reproduducibility:

Lot reproducibility was performed using two well-characterized strains of *M. tuberculosis* from CDC using two lots each of Myco broth and MYCO GS. Testing was performed in triplicate and on three separate days. The overall reproducibility was ≥ 95% for seeded inoculum.

Challenge Testing:

CDC challenge set of 30 organisms was tested at three sites. Of the possible 90 test points, only 77 were valid. The lower number of tests (7.2% repeat rate) was due to no growth, contamination or instrument issues. Of the 77 organisms tested, 68 were susceptible and 9 were resistant. There was an overall agreement of 98.7% with expected results

Clinical Isolate testing:

A total of 96 tests were performed on samples from seed bottle inoculum . The VersaTREK® MYCO PZA KIT demonstrated a category agreement of 88%.

Conclusions:

Data presented in this document demonstrates that the VersaTREK® MYCO PZA KIT is substantially equivalent to the BACTEC® 460 TB PZA Kit (k895362).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 8 2002

Mr. James L. Brown
Senior Vice President, Chief Operating Officer
Diagnostics Hybrids, Inc.
350 West State Street
Athens, OH 45701

Re: k022713
Trade/Device Name: Diagnostic Hybrids' DFA Respiratory Virus Screening and ID Kit
Regulation Number: 21 CFR 866.3330
Regulation Name: Influenza Virus Serological Reagents
Regulatory Class: Class I
Product Code: GNW
Dated: October 31, 2002
Received: November 1, 2002

Dear Mr. Brown:

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).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 19 2006

Ms. Nadine M. Sullivan
Chief Science Officer
TREK Diagnostic Systems, Inc.
210 Business Park Drive
Sun Prairie, WI 53590

Re: k052323
Trade/Device Name: Versa TREK® MYCO PZA KIT 300µ/ml
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test
Regulatory Class: Class II
Product Code: MJA
Dated: November 11, 2005
Received: December 2, 2005

Dear Ms. Sullivan:

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.

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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 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)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 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

Indications for Use

510(k) Number (if known): K052323
Device Name: VersaTREK® MYCO PZA KIT 300 µ/ml

Indications For Use:
The VersaTREK MYCO PZA KIT is a rapid qualitative procedure for susceptibility testing of *Mycobacterium tuberculosis*, from culture, to pyrazinamide (PZA).

The VersaTREK MYCO PZA KIT is used with the ESP Culture System II or with the VersaTREK Microbial Detection System. The VersaTREK MYCO PZA KIT final test concentration is 300 µg/ml for PZA.

Prescription Use _____X__ AND/OR Over-The-Counter Use

_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K052323