K021582

JUL 1 3 2002

510(k) SUMMARY

SUBMITTED BY: Becton Dickinson and Company
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CONTACT NAME: Michelle Bandy, Regulatory Affairs Specialist

DATE PREPARED: May 9, 2002

DEVICE TRADE NAME: BACTEC® MGIT™ 960 PZA Kit

DEVICE COMMON NAME: Antimicrobial susceptibility test powder

DEVICE CLASSIFICATION: 21 CFR§866.1640

PREDICATE DEVICE: BACTEC® 460TB PZA Kit

INTENDED USE:

The BACTEC® MGIT™ 960 PZA Kit is used as a rapid qualitative procedure for susceptibility testing of *Mycobacterium tuberculosis*, from culture, to pyrazinamide (PZA). The BACTEC® MGIT™ 960 PZA kit is used with the BACTEC® MGIT™ 960 System.

DEVICE DESCRIPTION:

The BACTEC® MGIT™ 960 PZA susceptibility test kit is used with the BACTEC® MGIT™ PZA Medium and performed on the BACTEC® MGIT™ 960 System. The PZA Medium tube is supplemented with BACTEC® MGIT™ 960 PZA Supplement and prepared with the appropriate dilution of pyrazinamide as the mechanism for performing the susceptibility test.

The BACTEC® MGIT™ 960 PZA susceptibility test utilizes a four to twenty-one day testing protocol. A standardized suspension of *Mycobacterium tuberculosis* growth is prepared from either solid or liquid culture media. An appropriate dilution is made of this suspension and 0.5 mL is inoculated into a Growth Control tube (drug-free) and a tube containing pyrazinamide (both tubes are referred to as an AST Set). The test interpretation is based on growth of the *Mycobacterium tuberculosis* isolate in the Growth Control tube compared to the growth in the drug-containing tube.

At the completion of the PZA susceptibility testing protocol, the instrument reports a susceptible or resistant result for the *Mycobacterium tuberculosis* isolate being tested.

DEVICE COMPARISON:

The BACTEC® MGIT™ 960 PZA susceptibility test is similar to the BACTEC® 460TB PZA susceptibility test in that:

- Both methods test drug susceptibility of *Mycobacterium tuberculosis* culture isolates.
- Both methods use the antimycobacterial drug pyrazinamide.
- Both methods compare organism growth in drug-free medium to organism growth in medium that contains the drug to obtain a susceptibility result.
- Both methods provide susceptibility results - susceptible (S) or resistant (R).
- Both methods utilize a four to twenty-one day protocol.
- Both methods test PZA using a drug concentration of 100 µg/mL.
- Both methods use Modified Middlebrook 7H9 Broth with a reduced pH.
- Both methods may use *Mycobacterium tuberculosis* isolates recovered from either solid or liquid source cultures.

The BACTEC® MGIT™ 960 PZA susceptibility test differs from the BACTEC® 460TB PZA susceptibility test method in that:

- The BACTEC® MGIT™ 960 PZA susceptibility test does not require user manipulation of the PZA test vials once entered into the instrument while the BACTEC® 460TB PZA susceptibility test requires off-line incubation and a daily manipulation of the PZA test bottles into the instrument for monitoring.
- The BACTEC® MGIT™ 960 PZA susceptibility test is continually monitored by the instrument while the BACTEC® 460TB PZA susceptibility test is monitored once daily.
- The BACTEC® MGIT™ 960 PZA susceptibility test uses an oxygen sensitive fluorescent sensor to monitor organism growth while the BACTEC® 460TB PZA susceptibility test uses radioactive labeled carbon dioxide ($^{14}CO_2$) to monitor organism growth.
- The BACTEC® MGIT™ 960 PZA susceptibility test data are automatically interpreted by the instrument software while the BACTEC® 460TB PZA susceptibility test data are manually calculated for result interpretation.
- The BACTEC® MGIT™ 960 PZA susceptibility test is performed using organism suspensions prepared directly from solid or liquid source while the BACTEC® 460TB PZA susceptibility test requires the solid or liquid source isolate to be subcultured into a BACTEC® 460TB 12B medium vial prior to performing the PZA susceptibility test.

SUMMARY OF SUBSTANTIAL EQUIVALENCE TESTING DATA:

Analytical Studies:

Reproducibility Testing

Reproducibility of the BACTEC® MGIT™ 960 PZA susceptibility test was evaluated using twenty-six qualified *Mycobacterium tuberculosis* strains (including three ATCC® strains). Three different lots of the reagents required to conduct the BACTEC® MGIT™ 960 PZA susceptibility test were evaluated. Observed results were compared to the expected results. The overall reproducibility was 96.8%.

CDC Challenge Panel Testing

The performance of the BACTEC® MGIT™ 960 PZA susceptibility test was evaluated using a panel of challenge strains obtained from the Centers for Disease Control and Prevention (CDC). Observed results were compared to the CDC expected results. The percent agreement was 98.7% to the CDC expected results.

Clinical Studies:

The BACTEC® MGIT™ 960 PZA susceptibility test was evaluated at four geographically diverse clinical sites, composed of regional reference centers and university-based laboratories.

Reproducibility Testing

The reproducibility of the BACTEC® MGIT™ 960 PZA Kit was evaluated at the clinical sites using a panel of five qualified strains. Observed results were compared to expected results. Overall reproducibility was 94%, with a range across sites of 86-100%.

CDC Challenge Panel Testing

The performance of the BACTEC® MGIT™ 960 PZA Kit was evaluated using a panel of challenge strains obtained from the Centers for Disease Control and Prevention (CDC). Observed results were compared to the CDC expected results. The percent agreement was 91.7% to the CDC expected results.

Clinical Isolate Testing

A total of 118 clinical strains of *Mycobacterium tuberculosis* were evaluated with the BACTEC® MGIT™ 960 PZA susceptibility test and the BACTEC® 460TB PZA test (reference method). This testing included fresh clinical and subculture isolates from both liquid and solid source cultures. A total of 228 PZA test results were generated and analyzed.

Category agreement was calculated for the isolates tested from both liquid and solid source cultures. The BACTEC® MGIT™ 960 PZA susceptibility test demonstrated a category agreement for liquid source culture of 98.2% and a category agreement of 95.6% for solid source culture.

The overall performance data demonstrate that the BACTEC® MGIT™ 960 PZA susceptibility test, used with the BACTEC® MGIT™ 960 System, is substantially equivalent[1] to the BACTEC® 460TB PZA susceptibility test (K895362).

[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the U.S. Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 13 2002

Ms. Michelle B. Bandy
Regulatory Affairs Specialist
BD Diagnostic Systems
Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

Re: k021582
Trade/Device Name: BACTEC® MGIT™ 960 PZA Kit
Pyrazinamide
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: MJA
Dated: May 13, 2002
Received: May 14, 2002

Dear Ms. Bandy:

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 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 Part 801); 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.

This letter will allow you to begin marketing your device as described in your 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 Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021582

Device Name: BACTEC® MGIT™ 960 PZA Kit

Indications for Use:

The BACTEC® MGIT™ 960 PZA Kit is a rapid qualitative procedure for susceptibility testing of *Mycobacterium tuberculosis*, from culture, to pyrazinamide (PZA).

The BACTEC® MGIT™ 960 PZA Kit is used with the BACTEC® MGIT™ 960 System. The BACTEC® MGIT™ 960 PZA Kit final test concentration is 100 µg/mL for pyrazinamide.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Ludolia N. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021582

*For Prescription Use ✓ (Optional Format 3-10-98)