K983772

JAN 13 1999

510(k) Premarket Notification
Organon Teknika Corporation
MB/BacT™ Blood Culture Bottle
Expanded Indication for use in the BacT/Alert Microbial Detection Systems

16.0 510(k) SUMMARY

A 510(k) Summary follows for the MB/BacT™ Blood Culture Bottle expanded indication for use in the BacT/Alert Microbial Detection System product described in this submission.

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510(k) Summary

(a)(1) **The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;**

Submitter's Name: Organon Teknika Corporation

Submitter's Address: 100 Akzo Avenue, Durham, North Carolina, 27712 USA

Submitter's Telephone: (919) 620-2288

Submitter's Contact: Rebecca Rivas

Date 510(k) Summary Prepared: 10/22/98

(a)(2) **The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known;**

Trade or Proprietary Name: MB/BacT™ Blood Culture Bottle

Common or Usual Name: Mycobacteria Blood Culture Bottle

Classification Name: Microbial Growth Monitor

(a)(3) **An identification of the legally marketed device to which the submitter claims substantial equivalence;**

Device Equivalent to: BACTEC 13A Blood Bottle - Becton Dickinson & Co.(K863191)

(a)(4) **A description of the device.**

Device Description: MB/BacT Blood Culture Bottles are specifically designed for the cultivation of Mycobacterium sp. Commonly isolated from blood.

(a)(5) **A statement of the intended use of the device.**

Device Intended Use: Recovery and detection of Mycobacteria from blood.

(a)(6) **A summary of the technological characteristics of the new device in comparison to those of the predicate device.**

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Assay Feature	*MB/BacT™Blood Culture Bottle*	*BACTEC 13A Blood Culture Bottle*
Specimen Source	Blood	Blood
Intended Use	Culture and detection of *Mycobacteria sp.* from blood.	Culture and detection of microorganisms *(mainly Mycobacteria)* from blood.
Sample Volume	3-5 mls.	5 mls.
Technology	Colorimetric sensor and reflectance values are used to monitor production of CO_2 dissolved in culture media.	Radiometric technique, $^{14}CO_2$ produced by Mycobacteria from the metabolism of ^{14}C-labeled substance is measured.
Storage	Culture Bottles – 15°C - 30°C Enrichment Fluid - 2°C - 8°C	Culture Bottles - 2°C - 25°C Enrichment Fluid - 2° - 25°C
Components	Culture Bottle and Enrichment Fluid	Culture Bottle and Enrichment Fluid
Controls	Certificate of Analysis provided , lab may test new lots if desired with ATCC#25291 and ATCC#13950 recommended days to positive provided in package insert.	Quality Control Certificates provided.

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(b)1) **A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.**

Testing was performed to establish the performance characteristics of the new device including:

A total of twenty mycobacterial isolates were tested representing ten different species. All isolates were evaluated in shaking conditions for two theoretical levels of inocula, 1 x 10^2 and 1 x 10^1 CFU, respectively. Overall, favorable growth performance was achieved with the cultures.

(b)(2) **A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalency.**

Two clinical studies were carried out yielding a total of 491 paired bottles. The studies compared growth of Mycobacteria sp. from blood between the MB/Blood Culture Bottle tested in a BacT/Alert Microbial Detection System (shaking environment) and the Bactec 13A. Out of the 491 paired bottles, 41 organisms were isolated by both the MB/Blood Bottle and the Bactec bottle. Seven (7) organisms were isolated by the MB/BacT Blood Bottle alone and 2 organisms were isolated by the Bactec 13A bottle alone.

(b)3) **The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performed as well or better than the legally marketed device identified in (a)(3).**

Both the MB/BacT Blood Culture Bottle and the predicate device, the Bactec 13A are equivalent in the following respects:

1. They have the same intended use: the recovery and detection of Mycobacteria in blood.
2. They are both in-vitro diagnostic test systems which are based on microbial growth in media.
3. Organon Teknika's MB/BacT Blood Culture Bottle when used on the BacT/Alert Microbial Detection System (shaking environment) yielded test results, both in clinical studies and in-house studies, comparable to that seen with the predicate device, the Bactec 13A Blood Culture Bottle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 13 1999

Rebecca A. Rivas
Regulatory Affairs Administrator
Organon Teknika Corporation
100 Akzo Avenue
Durham, NC 27712

Re: K983772
Trade Name: MB/BacT Blood Culture Bottle
Regulatory Class: I
Product Code: MDB
Dated: October 23, 1998
Received: October 26, 1998

Dear Ms. Rivas:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll free number (800) 638-2041 or at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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

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510(k) Number (If known):_____

Device Name: MB/BacT Blood Culture Bottle Expanded Indication for use on BacT/Alert Microbial Detection Systems

Indications For Use:

MB/BacT Blood Culture Bottles in combination with the MB/BacT Enrichment Fluid are specifically designed for the cultivation of *Mycobacterium sp.* commonly isolated from blood when used in conjunction with the MB/BacT Mycobacterial Detection Systems (non-shaking detection systems) and the BacT/Alert Microbial Detection Systems (shaking detection systems).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K98 3772

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)