K993576

DEC 14 1999

510(k) Premarket Notification
Organon Teknika Corporation
BacT/ALERT MP Process Bottle

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
Submitter's Telephone: (919) 620-2288

Submitter's Contact: Rebecca A. Rivas

Date 510(k) Summary Prepared: October 20, 1999

(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: BacT/ALERT MP Process Bottle

Common or Usual Name: BacT/ALERT MP Process 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: MB/BacT Process Bottles

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

Device Description: The BacT/ALERT MP Process Bottle was developed for the same intended use as the current MB/BacT Process Bottle, provide suitable nutritional and environmental conditions for mycobacterial organisms commonly encountered in body fluids. An inoculated bottle is placed into the MB/ BacT Detection Instrument or the BacT/ALERT 3D Instrument where it is incubated and continuously monitored for the presence of mycobacteria that will grow in the BacT/ALERT MP Process Bottle.

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

Device Intended Use: The BacT/ALERT MP Process Bottle is designed for use with the MB/BacT and the BacT/ALERT 3D Mycobacteria Detection Systems, for recovery and detection of mycobacteria from sterile body specimens other than blood, and from digested-decontaminated clinical specimens.

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

The BacT/ALERT MP Process Bottle utilizes the same detection technology as the MB/BacT/ Culture Bottle.

FEATURES	BACT/ALERT MP PROCESS BOTTLE	MB/BACT PROCESS BOTTLE
Technology	Reflectance	Reflectance
Color change based on CO_2 production	Yes	Yes
Sensor	Emulsion	Disc
Indicator material	Yes, Same as MB/BacT Process Bottle	Yes
Growth of microorganisms	Yes, Equivalent to MB/BacT Process Bottle	Yes
Instrument Used	MB/BacT Mycobacterial Detection Systems or BacT/ALERT 3D System	MB/BacT Mycobacterial Detection Systems or BacT/ALERT 3D System
Sample Source	Body Fluids	Body Fluids
Target Population	Adult	Adult

(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:

Seeded studies were performed on 12 organisms and inoculated into the BacT/ALERT MP Process Bottle and the MB/BacT Process Bottle.

(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).**

The BacT/ALERT MP Process Bottle was substantially equivalent to the MB/BacT Process Bottle based on recovery of the 12 mycobacterial organisms included in the study. Detection times were substantially equivalent in both bottles.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 14 1999

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

Re: K993576
Trade Name: BacT/ALERT MP Process Bottle
Regulatory Class: I
Product Code: MDB
Dated: October 20, 1999
Received: October 21, 1999

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

Page____of____

510(k) Number (If known): K993576

Device Name: BacT/ALERT MP Process Bottle

Indications For Use:

The BacT/ALERT MP Process Bottle is designed for use with the MB/BacT and the BacT/ALERT 3D Mycobacteria Detection Systems, for recovery and detection of mycobacteria from sterile body specimens other than blood, and from digested-decontaminated clinical specimens.

(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 K993576

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

(Optional Format 1-2-96)