SEP 3 1999

K992401

510(k) Premarket Notification
Organon Teknika Corporation
BacT/ALERT PF Culture 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:

(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 PF Culture Bottle

Common or Usual Name: BacT/ALERT PF 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: BacT/ALERT Pedi-BacT Culture Bottle

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

Device Description: The BacT/ALERT PF Culture Bottle provides a sensitive method for detection of microorganisms when only a small volume of blood is available. An inoculated bottle is placed into the instrument where it is incubated and continuously monitored for the presence of microorganisms that will grow in the BacT/ALERT PF Culture Bottle.

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

Device Intended Use: The BacT/ALERT PF Culture Bottles are used with the BacT/ALERT Microbial Detection Systems in qualitative procedures for enhanced recovery and detection of aerobic and facultative anaerobic microorganisms (bacteria and yeast) from blood.

(a)(6) **A summary of the technological characteristics of the new device in comparison to those of the predicate device.**
The BacT/ALERT PF Culture Bottle utilizes the same detection technology as the BacT/Alert Pedi-BacT Culture Bottle.

FEATURES	BACT/ALERT PF CULTURE BOTTLE	BACT/ALERT PEDI-BACT CULTURE BOTTLE
Technology	Reflectance	Reflectance
Color change based on CO_2 production	YES	YES
Sensor	Emulsion	Disc
Indicator material	Yes, Same as Pedi-BacT Bottle	Yes
Growth of microorganisms	Yes, Equivalent to Pedi-BacT Bottle	Yes
Instrument Used	BacT/ALERT Microbial Detection Systems	BacT/ALERT Microbial Detection Systems
Sample Source	Blood	Blood
Target Population	Pediatric	Pediatric

(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:

In-house seeded studies were performed utilizing 23 organisms seeded into BacT/ALERT PF and Pedi-BacT Culture Bottles. Two concentrations of organisms were seeded one at <100 CFU/bottle and the other at <10 CFU/bottle.

(b)3) **The conclusions drawn from the nonclinical 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).**

BacT/ALERT PF is substantially equivalent to Pedi-BacT Culture Bottles based on recovery of low levels of 23 microorganisms included in this study. The BacT/ALERT PF Culture Bottle has the same intended use and utilizes the same detection methodology as the current Pedi-BacT/Alert Culture Bottle. The BacT/ALERT PF Culture Bottle is a modified version of the current Pedi-BacT Culture Bottle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 3 1999

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

Re: K992401
Trade Name: BacT/ALERT PF Culture Bottle
Regulatory Class: I
Product Code: MDB
Dated: July 16, 1999
Received: July 19, 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

510(k) Number (If known):_____

Device Name: BacT/ALERT PF Culture Bottle

Indications For Use:

The BacT/ALERT PF Culture Bottles are used with the BacT/ALERT Microbial Detection Systems in qualitative procedures for enhanced recovery and detection of aerobic and facultative anaerobic microorganisms (bacteria and yeast) from blood.

(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 K992401

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

(Optional Format 1-2-96)