K973325

510(k) Premarket Notification
Organon Teknika Corporation
BacT/Alert™ FAN Culture Bottles

510(k) Summary
BacT/Alert® FAN™ Culture Bottles

DEC - 2 1997

(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 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® FAN™ Culture Bottle

Common or Usual Name: Culture Bottles

Classification Name: Microbial Growth Monitor

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

Device Equivalent to: Traditional Culture Methodology

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

Device Description: The BacT/Alert® FAN Culture Bottles contain media, an adsorbent and an internal sensor that detects CO_2 as an indicator of microbial growth when used in connection with the BacT/Alert® Microbial Detection System.

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

Device Intended Use: BacT/Alert® FAN™ Culture Bottles are used with the BacT/Alert® Microbial Detection System in qualitative procedures for enhanced recovery and detection of aerobic and anaerobic microorganisms from blood and other body fluids.

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

The BacT/Alert® FAN Culture Bottles contain media, an adsorbent and an internal sensor that detects CO_2 as an indicator of microbial growth when used in connection with the BacT/Alert® Microbial Detection System.

(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.**

Testing was performed to establish the performance characteristics of the new device including comparison to traditional culture.

(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).**

Organon Teknika's BacT/Alert® FAN Culture Bottles are used with the BacT/Alert® Microbial Detection System in qualitative procedures for enhanced recovery and detection of aerobic and anaerobic microorganisms from blood and other body fluids. It is substantially equivalent to conventional culture methodologies.

The methods are equivalent in the following respects:

1. They have the same intended use: recovery and detection of aerobic and anaerobic microorganisms from body fluids.

2. They are both in-vitro diagnostic test systems which are based on microbial growth in media.

3. Organon Teknika's BacT/Alert® FAN Culture Bottles yield test results comparable to that seen with conventional culture methodology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC - 2 1997

Rebacca A. Rivas
Regulatory Specialist
Organon Teknika Corp.
100 Akzo Ave.
Durham, NC 27712

Re: K973325
Trade Name: Bact/Alert Fan Culture Bottles
Regulatory Class: I
Product Code: MDB
Dated: November 7, 1997
Received: November 10, 1997

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 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): K97 3325

Device Name: BACT/ALERT FAN Culture Bottles (expanded indications)

Indications For Use:

BacT/Alert FAN Culture Bottles are used with the BacT/Alert Microbial Detection System in qualitative procedures for enhanced recovery and detection of aerobic and anaerobic microorganisms from blood and other body fluids.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR Over-The-Counter Use____

(Optional Format 1-2-96)

John Ticehurst, Med Officer & Interim Chief MICB
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973325