

JUL 24 1998

510(k) PREMARKET NOTIFICATION  
BACT/ALERT 3D SYSTEM  
EXPANDED INDICATION FOR MYCOBACTERIA

K981736

16.0 510(K) SUMMARY

A 510(k) Summary follows for the BacT/Alert 3D with Mycobacteria Indication described in this submission.

**510(k) PREMARKET NOTIFICATION  
BACT/ALERT 3D SYSTEM  
EXPANDED INDICATION FOR MYCOBACTERIA**

**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: Organon Teknika Corporation  
100 Akzo Avenue  
Durham, North Carolina 27712**

**Submitter's Telephone: (919) 620-2288**

**Submitter's Contact: Rebecca Rivas**

**Date 510(k) Summary Prepared: May 15, 1998**

- (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 3D**

**Common or Usual Name: BacT/Alert 3D**

**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 Mycobacteria Culture System**

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

**Device Description: BacT/Alert 3D System with expanded Mycobacteria indication is used in the qualitative procedures for growth and detection of Mycobacteria in clinical specimens other than blood.**

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

**Device Intended Use: Used in qualitative procedures for growth and detection of Mycobacteria in clinical specimens other than blood.**

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

	<i>MB/BacT Mycobacteria System</i>	<i>BacT/Alert 3D with Mycobacteria Indication</i>
<i>Intended Use</i>	Growth and detection of Mycobacteria in Clinical Specimens other than blood.	Growth and detection of Mycobacteria in Clinical Specimens other than blood.
<i>Media</i>	MB/BacT Process bottles (K954468), Culture Media with suitable nutritional conditions to recover mycobacterial species. Containing Middlebrook 7H9 Broth, Pancreatic Digest of Casein, Bovine Serum Albumin, Catalase, Purified Water.	MB/BacT Process bottles (K954468), Culture Media with suitable nutritional conditions to recover mycobacterial species. Containing Middlebrook 7H9 Broth, Pancreatic Digest of Casein, Bovine Serum Albumin, Catalase, Purified Water.
<i>Bottle Blocks</i>	Sealed for spill control	Sealed for spill control
<i>Air Circulation</i>	Shuts off when door is open	Shuts off when drawer is open
<i>Determination for positivity</i>	High enough amount of acceleration of CO <sub>2</sub> production, High enough amount of long-term growth, and high enough total change (delta) in the growth curve.	High enough amount of acceleration of CO <sub>2</sub> production, High enough amount of long-term growth, and high enough total change (delta) in the growth curve.

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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: Seeded studies were performed in-house for 10 organisms at inoculum levels of  $10^6$  (high) and  $10^2$  (low) CFU/ml. Individual strains of each organism at the low inoculum level were inoculated into six bottles each. Three bottles were loaded into the current MB/BacT system, and three were loaded into the BacT 3D instrument. Individual strains of each organism at the high inoculum level were inoculated into two bottles each. One bottle was loaded into the current MB/BacT system, and one bottle was loaded into the BacT 3D instrument. Times to detection (in days) for each bottle were used to perform analysis for substantial equivalence between the two systems. Analysis of the ranks of the times to detection showed no significant effect of detection system for either the high or low inoculum level.

- 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.**

A total of 311 isolates were cultured from clinical specimens on both the BacT/Alert 3D and the MB/BacT Mycobacteria Culture System. 22 isolates were positive on both the BacT/Alert 3D and the MB/BacT. An additional 14 isolates were found to be positive on the BacT/Alert 3D only. 8 additional isolates were found to be positive on the MB/BacT only.

- (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 3D System with mycobacteria indication utilizes the same culture media bottles and detection algorithms as the currently marketed predicate device the MB/BacT Mycobacteria Culture System.

Both systems are equivalent in the following respects:

1. They both have the same intended use: For use in qualitative procedures for growth and detection of mycobacteria in clinical specimens other than blood.
2. They both utilize the same culture media bottles and detection methodology.
3. The BacT/Alert 3D yielded test results comparable to that seen with the predicate device the MB/BacT Mycobacteria Culture System.



JUL 24 1998

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

Re: K981736  
Trade Name: BacT/Alert 3D with Mycobacteria Indication  
Regulatory Class: I  
Product Code: MDB  
Dated: June 24, 1998  
Received: June 25, 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 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.

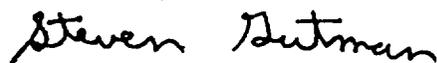
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, 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 (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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): K981736

Device Name: BACT/ALERT 3D WITH MYCOBACTERIA INDICATION

Indications For Use:

THE BACT/ALERT 3D MICROBIAL DETECTION SYSTEM WITH EXPANDED MYCOBACTERIA INDICATION IS USED IN QUALITATIVE PROCEDURES FOR GROWTH AND DETECTION OF MYCOBACTERIA IN CLINICAL SPECIMENS OTHER THAN BLOOD.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)  
Division of Clinical Laboratory Devices

510(k) Number K981736

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)