K003306

NOV 22 2000

510(k) Summary of the *C. Difficile TOX A/B II* Evaluation

The purpose of this study was to evaluate modifications to the *TOX A/B TEST* (K971182) on test performance. Our evaluation demonstrates the following:

- The replacement of the two component substrate with a single component substrate makes the test easier to perform and does not change test performance. In conjunction with the one component substrate, the Stop Solution was modified from 1 M sulfuric acid to 0.6 N sulfuric acid as recommended by the substrate manufacturer

- Changing the incubation period from 30-minutes to 20-minutes in the rapid format shortens the turn-around time for the user but does not change the test performance.

- The STOOL-PREP, an optional dilution device, can be used to sample the specimen from the container as an alternative method for stool processing. It uses the same Diluent as the cleared device and it offers the user a simpler and safer method for processing stool specimens.

- The modified test is named the *C. difficile TOX A/B II* and it has the same Intended Use as the cleared device.

In summary, our results show that these modifications do not affect the performance of the test.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 22 2000

David M. Lyerly, Ph.D.
Vice President
TechLab, Inc.
1861 Pratt Drive
Suite 1030
Blacksburg, Virginia 24060-6364

Re: K003306
Trade Name: C. difficile TOX A/B II
Regulatory Class: I
Product Code: LLH
Dated: November 3, 2000
Received: November 6, 2000

Dear Dr. Lyerly:

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.

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" (21CFR 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/dsma/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): K 003306

Device Name: *C. difficile TOX A/B II*

Indications For Use:

The *TOX A/B II* is an enzyme immunoassay for the rapid detection of toxins A and B produced by toxigenic strains of *Clostridium difficile*. It can be used to detect toxins A and B in fecal specimens from persons suspected of having *C. difficile* disease. The test is to be used as an aid in the diagnosis of *C. difficile* disease and results should be considered in conjunction with the patient history. FOR IN VITRO DIAGNOSTIC USE.

(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 K003306

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)