K971182

6. SMDA INFORMATION

JUL 22 1997

6.1 510(k) Summary

The purpose of this study was to evaluate the *TOX A/B TEST* developed by TechLab. Our evaluation demonstrates the following:

- The *TOX A/B TEST* is specific for toxins A and B of *Clostridium difficile* or the equivalent toxins of toxigenic *C. sordellii*. The test does not react with antigens from nontoxigenic strains of *C. difficile* or antigens from members of the normal intestinal flora or enteric pathogens.

- The *TOX A/B TEST* exhibits a sensitivity and specificity of 92% and 100%, respectively, when compared with the "gold standard" tissue culture test. It demonstrates predictive positive and negative values of 100% and 99%, respectively, and a correlation of > 98% when compared with the tissue culture test.

- The *TOX A/B TEST* can be completed within 1 hour, providing the clinical laboratory with rapid and reliable results.

- The *TOX A/B TEST* minimizes the number of steps needed, making it easy to use.

- The TOX A/B TEST has been optimized so that an indeterminate zone is not needed, thus simplifying the interpretation of test results.

In summary, the *TOX A/B TEST* represents a new test that offers the advantages of improved performance and ease-of-use over existing *C. difficile* tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

David M. Lyerly, Ph.D.
Techlab, Inc.
1861 Pratt Drive
Corporate Research Center
Blacksburg, VA 24060

JUL 22 1997

Re: K971182
Trade Name: Tox A/BTest
Regulatory Class: I
Product Code: LLH
Dated: June 6, 1997
Received: June 9, 1997

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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

2. STATEMENT OF INTENDED USE

510(k) Number (if known): Not known

Device Name: *TOX A/B TEST*

Indications For Use:

The *TOX A/B TEST* is an enzyme immunoassay for the 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)

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number _____