Summary of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K030404.

This product, *C. DIFFICILE TOX A/B II* test, was used with the Adaltis Personal Lab Jr. automated microplate analyzer system.

The equivalent predicate device 510(k) numbers are K003306, K971182, and K971761 respectively.

The *C. DIFFICILE TOX A/B II* test is an enzyme-linked immunoassay for the detection of toxins A and B in fecal specimens from patients suspected of having *C. difficile* disease and can be used either manually or with the Adaltis Personal Lab Jr. automated microplate analyzer system for ease of use.

The subject test kit is an enzyme-linked immunoassay and has not been modified from the predicate device (K003306 and K971182). It has no technological differences from the prior 510(k) applications.

The automated microplate analyzer system was not modified for use with this assay. The K971761 510(k) describes the software validation study, which has not been modified for this assay.

The *C. DIFFICILE TOX A/B II* test was tested with pre-characterized fecal samples both manually and with four of the same model of automated microplate analyzer system by three different people. The results of these evaluations show a positive sample correlation of > 97% and a negative sample correlation of > 99% between the manual and automated methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 25 2003

Mr. David A. Wall
Vice-President of Operations
TECHLAB, Inc.
VPI Research Park
1861 Pratt Drive, Suite 1030
Blacksburg, VA 24060-6364

Re: k030404
Trade/Device Name: C. Difficile Tox A/B II
Regulation Number: 21 CFR 866.2660
Regulation Name: Microorganism Differentiation and Identification Device
Regulatory Class: Class I
Product Code: LLH
Dated: February 5, 2003
Received: February 6, 2003

Dear Mr. Wall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

2.0 STATEMENT OF INTENDED USE

510(k) Number (if known): K030404

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

Indications For Use:

The *C. DIFFICILE TOX A/B II* test is an enzyme immunoassay for the detection of toxins A and B produced by toxigenic strains of *Clostridium difficile* in fecal specimens from persons suspected of having *C. difficile* disease and results should be considered in conjunction with the patient history. The test may be performed using either manual or automated (*PersonalLab Junior*, Adaltis U.S. Inc.) methods.
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 ✓ (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Clinical Laboratory Devices

Over-The Counter Use _____

510(k) Number K030404 (Optional format 1-2-96)