K032811

NOV 2 4 2003

SECTION II

510(k) SUMMARY

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

510(k) Number:

Submitter:
Microgenics Corporation
46360 Fremont Blvd
Fremont, CA 94538
Telephone: (510)-979-5012
Facsimile: (510) 979-5212

Contact Person:

David Casal, Ph.D.
Vice-President, Clinical, Regulatory and Quality Affairs
Telephone: (510)-979-5012
Facsimile: (510) 979-5212

Preparation Date:

September 8, 2003

Device Information:

Device Classification Name:	Radioimmunoassay, Vancomycin
Common/Usual Name:	Vancomycin Immunoassay Test System
Proprietary Name:	CEDIA® Vancomycin Assay
Regulation Number:	21 CFR§862.3950
Regulatory Name:	Vancomycin tesystem
Product Code:	LEH
Regulatory Class:	Class II

Predicate Devices:

The CEDIA® Vancomycin Assay is substantially equivalent to the AxSYM® Vancomycin II (Abbott Diagnostics, Abbott Park, IL) (K955851) for its stated intended use.

Device Description:

The CEDIA® Vancomycin Assay uses recombinant DNA technology (US Patent No. 4708929) to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments i.e., enzyme acceptor (EA) and enzyme donor (ED). These fragments spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.

In the assay, analyte in the sample competes with analyte conjugated to one inactive fragment of β-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragments free to form active enzyme. If analyte is not present in the sample, antibody binds to analyte conjugated on the inactive fragment, inhibiting the reassociation of inactive β-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of drug present in the sample.

Intended Use:

The CEDIA® Vancomycin Assay is a homogenous enzyme immunoassay intended for in vitro diagnostic use in the quantitative determination of vancomycin in human serum or plasma for the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.

Comparison to Predicate Device(s):

The CEDIA® Vancomycin Assay is substantially equivalent to the Abbott AxSYM® Vancomycin II (K955851) in its intended use and principle of use.

Device Characteristics	Subject Device	Predicate Device (K955851)
Intended Use	The CEDIA® Vancomycin Assay is a homogenous enzyme immunoassay intended for in vitro diagnostic use in the quantitative determination of vancomycin in human serum or plasma for the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.	AxSYM® Vancomycin II (K955851) is a reagent system for the quatitative measurement of vancomycin, an antibiotic drug, in serum or plasma. The measurements obtained are used in the diagnosis and treatment of vancomycin overdose and in monitoring levels of vancomycin to ensure appropriate therapy.
Analyte	Vancomycin	Vancomycin
Matrix	Serum or plasma	Serum or plasma
Calibrator Form	Liquid	Liquid
Calibrator Levels	Two (2) Levels (0 and 50 µg/mL)	Six (6) Levels
Storage	2°C to 8°C until expiration date	2°C to 8°C until expiration date
Stability	Until expiration date noted on vial label and Package Insert for Kit and reconstituted reagents.	Until expiration date noted on vial label.

Summary:

The information provided in this pre-market notification demonstrates that the CEDIA® Vancomycin Assay is substantially equivalent to the Abbott AxSYM® Vancomycin II assay, the previously cleared predicate device (K955851). Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available predicate device. The information supplied in this pre-market notification provides reasonable assurance that the CEDIA® Vancomycin Assay is safe and effective for its stated intended use.

CEDIA® is a registered trademark of Roche Diagnostics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 2 4 2003

David Casal, Ph.D.
VP, Clinical, Regulatory and Quality Affairs
Microgenics Corporation
46360 Fremont Blvd.
Fremont, CA 94538

Re: k032811
Trade/Device Name: CEDIA® Vancomycin Assay
Regulation Number: 21 CFR 862.3950
Regulation Name: Vancomycin test system
Regulatory Class: Class II
Product Code: LEH
Dated: September 8, 2003
Received: September 12, 2003

Dear Dr. Casal:

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). You may obtain other general information on your responsibilities under the Act 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

SECTION III

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device name: CEDIA® Vancomycin Assay

Indications for Use:

The CEDIA® Vancomycin Assay is a homogenous enzyme immunoassay intended for in vitro diagnostic use in the quantitative determination of vancomycin in human serum or plasma for the diagnosis and treatment of vancomycin overdose and in monitoring the level of vancomycin to ensure appropriate therapy.

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) k032811

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)