K032842

OCT 17 2003

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
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Contact Person:

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

September 10, 2003

Device Information:

Device Classification Name:	Drug Specific Control Materials
Common/Usual Name:	Cyclosporine Immunosuppressive Drug Control
Proprietary Name:	Microgenics Cyclosporine Controls
Regulation Number:	21 CFR§862.3280
Regulatory Name:	Clinical toxicology control material
Product Code:	LAS
Regulatory Class:	Class I

Predicate Devices:

CEDIA® Cyclosporine Plus High Range Controls 4 and 5 (K030616) Lyphochek® Whole Blood Control (K022041) manufactured by Bio-Rad Laboratories.

Device Description:

The Microgenics Cyclosporine Controls are prepared from whole human blood, with pure chemicals stabilizers added. The control kit includes five separate controls known as C_1, C_2, C_3, C_4 and C_5 with target concentrations of approximately 70, 200, 350, 700 and 1600

ng cyclosporine/mL. The Microgenics Cyclosporine Controls are provided in lyophilized form for increased stability.

Intended Use:

The Microgenics Cyclosporine Controls, consisting of levels 1 through 5, are in-vitro diagnostic medical devices intended for use as assayed quality control material to monitor the precision of laboratory testing procedures for cyclosporine.

Comparison to Predicate Device(s):

The Microgenics Cyclosporine Controls are substantially equivalent to the CEDIA® Cyclosporine Plus High Range Controls 4 and 5 (K030616) and the Lyphochek® Whole Blood Control (K022041) manufactured by Bio-Rad Laboratories. Moreover, the Microgenics Cyclosporine Controls are manufactured using methods virtually identical to those used for manufacture of the CEDIA® Cyclosporine Plus High Range Controls 4 and 5.

Device Characteristics	Subject Device	Predicate Device (K030616)	Predicated Device (K022041)
Intended Use	Microgenics Cyclospor-ine Controls, consisting of levels 1 through 5, are in-vitro diagnostic medical devices intended for use as assayed quality control material to monitor the precision of laboratory testing procedures for cyclosporine.	CEDIA® Cyclosporine Plus High Range Controls are intended for use as an assayed quality control material to monitor the precision of laboratory procedures for cyclosporine.	Lyphochek® Whole Blood Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for cyclosporine.
Matrix	Processed Human Whole Blood	Processed Human Whole Blood	Processed Human Whole Blood
Form	Lyophilized	Lyophilized	Lyophilized
Analytes	Cyclosporine	Cyclosporine	Cyclosporine, Lead, Red Call Folate, and Tacrolimus
Levels	Five (5) Levels	Two (2) Levels	Three (3) Levels
Reconstituted Vial Claim	14 days at 2°C to 8°C	14 days at 2°C to 8°C	14 days at 2°C to 8°C. Exception: Red cell folate is stable for 3 days at 2°C to 8°C
Storage	2°C to 8°C until expiration date	2°C to 8°C until expiration date	2°C to 8°C until expiration date
Stability	Until expiration date noted on vial label.	Until expiration date noted on vial label.	Until expiration date noted on vial label.

Summary:

The information provided in this pre-market notification demonstrates that the Microgenics Cyclosporine Controls (Assayed and Unassayed) are substantially equivalent to the previously cleared predicate devices. Substantial equivalence was demonstrated through comparison of intended use and physical properties to commercially available devices. The information supplied in this pre-market notification provides reasonable assurance the Microgenics Cyclosporine Controls are safe and effective for the 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

OCT 17 2003

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

Re: k032842
Trade/Device Name: Microgenics Cyclosporine Controls
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical toxicology control material
Regulatory Class: Class I
Product Code: LAS
Dated: September 10, 2003
Received: September 16, 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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K032842

Device name: Microgenics Cyclosporine Controls

Indications for Use:

The Microgenics Cyclosporine Controls, consisting of levels 1 through 5, are in-vitro diagnostic medical devices intended for use as assayed quality control material to monitor the precision of laboratory testing procedures for cyclosporine.

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 for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032842