JUN 6 - 2005

510(k) SUMMARY

K051074

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)-979-5000

Contact Person:

Lisa Charter
Research and Development
46360 Fremont Blvd.
Telephone: (510)-979-5142
Facsimile: (510) 979-5455

Preparation Date:

April 25, 2005

Device Information:

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

Predicate Devices:

Lyphochek® Whole Blood Control (K022041) manufactured by Bio-Rad Laboratories.

Device Description:

MAS Immunosuppressant Controls is prepared from human whole blood, with pure chemicals and stabilizers. The control is provided in a liquid form containing Cyclosporine, Sirolimus, and Tacrolimus.

Intended Use:

The MAS Immunosuppressant Controls, consisting of levels 1 through 3, are in-vitro diagnostic medical devices intended for use as assayed quality control material to monitor the precision of laboratory testing procedures for cyclosporine, sirolimus, and tacrolimus.

Comparison to Predicate Device(s):

The Microgenics Cyclosporine Controls are substantially equivalent to Lyphochek® Whole Blood Control (K022041) manufactured by Bio-Rad Laboratories.

Device Characteristics	Subject Device	Predicated Device (K022041)
Intended Use	The MAS Immunosuppressant Controls, consisting of levels 1 through 3, are in-vitro diagnostic medical devices intended for use as assayed quality control material to monitor the precision of laboratory testing procedures for cyclosporine, sirolimus, and tacrolimus.	Lyphochek® Whole Blood Control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for cyclosporine, lead, red cell folate, tacrolimus, and sirolimus.
Matrix	Processed Human Whole Blood	Processed Human Whole Blood
Form	Liquid	Lyophilized
Analytes	Cyclosporine, Sirolimus, Tacrolimus	Cyclosporine, Lead, Red Cell Folate, Tacrolimus, Sirolimus
Levels	Three (3) Levels	Three (3) Levels
Open Vial Claim	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	-20°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.

Summary:

The information provided in this pre-market notification demonstrates that the MAS Immunosuppressant Controls 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 MAS Immunosuppressant Controls are safe and effective for the stated intended use.

MAS® is a registered trademark of Medical Analysis Systems, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 6 - 2005

Ms. Lisa Charter
Research and Development
Microgenics Corporation
46360 Fremont Blvd
Fremont, CA 94538

Re: k051074
Trade/Device Name: MAS Immunosuppressant Controls
Regulation Number: 21 CFR 862.3280
Regulation Name: Clinical toxicology control material
Regulatory Class: Class I
Product Code: LAS
Dated: April 25, 2005
Received: April 29, 2005

Dear Ms. Charter:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051074

Device Name: MAS Immunosuppressant Controls

Indications For Use:

The MAS Immunosuppressant Controls, consisting of levels 1 through 3, are in-vitro diagnostic medical devices intended for use as assayed quality control material to monitor the precision of laboratory testing procedures for cyclosporine, sirolimus, and tacrolimus.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

G. Chesler

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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