510K SUMMARY

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: K081083

COMPANY/CONTACT PERSON

Thermo Fisher Scientific
Microgenics Corporation
46360 Fremont Blvd.
Fremont, CA 94538

DEC 19 2008

Establishment registration No: 2937369

Jack Rogers
Manager of Regulatory Affairs
Telephone: (317) 610-3823
Fax: (317) 610-0018

DATE PREPARED

November 4, 2008

DEVICE NAME

Trade Name:	CEDIA® Mycophenolic Acid Assay
	CEDIA® Mycophenolic Acid Calibrators
	MAS® Mycophenolic Acid Controls
Common Name:	Mycophenolic Acid Test System
Device Classification:	21 CFR 862.3840 Mycophenolic Acid Test System; Class II
	21 CFR 862.3200 Clinical Toxicology Calibrator; Class II
	21 CFR 862.3280 Clinical Toxicology Control Material; Class I

INTENDED USE

The **CEDIA Mycophenolic Acid Assay** is an in vitro diagnostic medical device intended for the quantitative measurement of mycophenolic acid in human plasma using automated clinical chemistry analyzers as an aid in the management of mycophenolic acid therapy in renal and cardiac transplant patients.

The **CEDIA Mycophenolic Acid Calibrators** are intended for use in the calibration of the CEDIA MPA Assay.

The **MAS Mycophenolic Acid Controls** are intended for use as assayed quality control material for validation of MPA assays

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCY IS CLAIMED

Roche Total Mycophenolic Acid assay (K063520)

DESCRIPTION OF DEVICE

The *CEDIA Mycophenolic Acid Assay* is a homogeneous assay based on the enzyme β-galactosidase, which has been genetically engineered into two inactive fragments termed enzyme donor (ED) and enzyme acceptor (EA). These fragments spontaneously re-associate to form fully active enzymes that, in assay format, cleave a substrate, generating a color change that can be measured spectrophotometrically.

The assay consists of a set of four reagents: Enzyme Acceptor Buffer, Enzyme Acceptor Reagent, Enzyme Donor Buffer, and Enzyme Donor Reagent. A two-level (Low and High) set of calibrators is used to calibrate the assay. A three-level set of controls (1 through 3) is used for quality control of the assay.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Comparison	CEDIA Mycophenolic Acid Assay	Predicate Device – Roche Mycophenolic Acid Assay
Intended Use	Quantitative measurement of mycophenolic acid in human plasma using automated clinical chemistry analyzers as an aid in the management of mycophenolic acid therapy in renal and cardiac transplant patients.	Quantitative determination for total mycophenolic acid in human serum or plasma as an aid in the management of mycophenolic acid therapy in renal and cardiac transplant patients.
Test Principle	Enzyme immunoassay with MPA concentration directly proportional to the assay signal (absorbance change).	Enzyme-mimicking assay with MPA concentration inversely proportional to the assay signal (absorbance change).
Matrix	Human plasma	Non-hemolyzed human serum or plasma
Reagents	Two reagent assay	Two reagent assay
Calibrators	Two levels (0 and 10 µg/mL)	Six levels (0, 1, 3, 5, 10, 15 µg/mL)
Controls	Liquid plasma-based (1.0, 2.5, 6.0 µg/mL)	Liquid serum-based (0.86, 3.40, 11.96 µg/mL)
Assay Range	0.2 to 10.0 µg/mL	0.4 to 15 µg/mL

CONCLUSION

As summarized, the *CEDIA Mycophenolic Acid Assay* is substantially equivalent to the *Roche Total Mycophenolic Acid assay*. Substantial equivalence has been demonstrated through performance testing to verify that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Thermo Fisher Scientific
Microgenics Corporation
c/o Mr. Jack Rogers
Manager of Regulatory Affairs
46360 Fremont Blvd.
Fremont, CA 94538

DEC 19 2008

Re: k081083
Trade/Device Name: Cedia Mycophenolic Acid Assay, Mycophenolic Acid Calibrators, Mas Mycophenolic Acid Controls
Regulation Number: 21 CFR 862.3840
Regulation Name: Sirolimus Test System.
Regulatory Class: Class II
Product Code: OAV, DLJ, LAS
Dated: November 11, 2008
Received: November 12, 2008

Dear Mr. Rogers:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
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): K081083

Device Name: CEDIA Mycophenolic Acid Assay

Indications for Use:

The **CEDIA Mycophenolic Acid Assay** is an in vitro diagnostic medical device intended for the quantitative measurement of mycophenolic acid in human plasma using automated clinical chemistry analyzers as an aid in the management of mycophenolic acid therapy in renal and cardiac transplant patients.

The **CEDIA Mycophenolic Acid Calibrators** are intended for use in the calibration of the CEDIA MPA Assay.

The **MAS Mycophenolic Acid Controls** are intended for use as assayed quality control material for validation of MPA assays.

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K081083