K023208

OCT 2 4 2002

510(k) 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: K_____

Submitter Information (21 CFR 807.92(a)(1))

Submitter: Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538
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Contact: Name
Regulatory Specialist

Summary date: June 11, 2002

Name of Device and Classification (21 CFR 807.92(a)(2))

Name (trade): CEDIA® Cyclosporine Plus Assay

Name (usual): Cyclosporine Assay

Classification: Unknown

Identification of Legally Marketed Predicate Device(s) (21 CFR 807.92 (a)(3))

CEDIA Cyclosporine Plus Assay is substantially equivalent to EMIT 2000 Cyclosporine Specific Assay (Dade Behring Inc., San Jose, CA), cleared under premarket notification P920031

CEDIA Cyclosporine Plus Assay is identical or similar to its predicate in terms of intended use, method principle, device components, risk to the patient, and clinical performance.

Description of Device (21 CFR 807.92 (a)(4))

The CEDIA Cyclosporine Plus Assay is a two-reagent set intended to be used with automated clinical chemistry analyzers. The 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 ß - galactosidase, which has been genetically engineered into two inactive fragments. These fragments, termed Enzyme Acceptor (EA) and Enzyme Donor (ED) spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate, to generate a color change that can be measured spectrophotometrically.

In the CEDIA Cyclosporine Plus Assay, drug in the sample competes with drug conjugated to ED for antibody binding sites. If drug is present in the sample, it binds to antibody, leaving the ED–drug conjugate free to reassociate with EA to form active ß-galactosidase. If no drug is present in the sample, antibody binds to the ED–cyclosporine conjugate, inhibiting the reassociation of inactive ß-galactosidase fragments, and thus reducing the amount of active enzyme formed. The amount of active enzyme formed, and resulting absorbance change, is proportional to the amount of CEDIA Cyclosporine Plus Assay present in the sample.

Intended Use (21 CFR 807.92 (a)(5))

The CEDIA Cyclosporine Plus Assay is for the quantitative determination of cyclosporine in human whole blood using automated clinical chemistry analyzers as an aid in the management of therapy in kidney, liver, and heart transplants. The CEDIA Cyclosporine Calibrators are used to calibrate the CEDIA Cyclosporine Plus Assay in human whole blood.

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))

A summary table of the similarities and difference between CEDIA Cyclosporine Plus Assay and the predicate device follows.

Comparison Table:

CEDIA Cyclosporine Plus Assay vs. EMIT 2000 Cyclosporine Specific Assay

Device Name	EMIT 2000 Cyclosporine Specific Assay (P920031)	CEDIA Cyclosporine Plus Assay (new device)
Indications for Use	The Emit 2000 Cyclosporine Specific Assay is for in vitro diagnostic use on the Roche Diagnostics Systems COBAS MIRA, COBAS MIRA S and COBAS MIRA Plus chemistry systems for the quantitative analysis of cyclosporine (CsA) in human whole blood as an aid in the management of cyclosporine therapy in kidney, heart, and liver transplants.	The CEDIA Cyclosporine Plus Assay is for the quantitative determination of cyclosporine in human whole blood using automated clinical chemistry analyzers as an aid in the management of therapy in kidney, liver, and heart transplants. The CEDIA Cyclosporine Calibrators are used to calibrate the CEDIA Cyclosporine Plus Assay in human whole blood.
Method Principle	The assay uses a mouse monoclonal antibody with specificity to cyclosporine and a second mouse monoclonal antibody specific for a major metabolite of cyclosporine, AM9 (M1) to prevent metabolite binding to the primary antibody. The assay is based on competition for cyclosporine antibody binding sites between analyte in the sample and cyclosporine labeled with G6-PDH. Active (unbound) enzyme converts NAD to NADH, resulting in an absorbance change measured	The CEDIA Cyclosporine Plus Assay is a two-reagent set intended to be used with automated clinical chemistry analyzers. The 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 ß -galactosidase, which has been genetically engineered into two inactive fragments. These fragments, termed Enzyme Acceptor (EA) and Enzyme Donor (ED),

Device Name	EMIT 2000 Cyclosporine Specific Assay (P920031)	CEDIA Cyclosporine Plus Assay (new device)
Method Principle, continued	spectrophotometrically. Before testing, samples are pretreated with methanol. The pretreatment lyses the cells, solubilizes the cyclosporine, and precipitates most of the blood proteins. The samples are centrifuged, and an aliquot of the resulting supernatant is then assayed	(EA) and Enzyme Donor (ED), spontaneously reassociate to form fully active enzyme, which, in the assay format, cleaves a substrate to generate a color change that can be measured spectrophotometrically. In the CEDIA Cyclosporine Plus Assay, cyclosporine in the sample competes with the cyclosporine conjugated to ED for antibody binding sites. If cyclosporine is present in the sample, it binds to the antibody, leaving the ED–cyclosporine conjugate free to reassociate with EA to form active ß-galactosidase. If no cyclosporine is present in the sample, antibody binds to the ED–conjugate, inhibiting the reassociation of inactive ß-galactosidase fragments, and thus reducing the amount of active enzyme formed. The amount of active enzyme formed and the resulting absorbance change are proportional to the amount of cyclosporine present in the sample. The pretreatment reagent lysis the cell and solubilizes the whole blood for testing.
Components	- Reagent A - Enzyme B Reagent	- Enzyme Acceptor Reagent - Enzyme Acceptor Buffer - Enzyme Donor Reagent - Enzyme Donor Buffer - Lysing Reagent
Risk to patient	An in vitro diagnostic device that can be used as an aid in the management of cyclosporine therapy.	An in vitro diagnostic device that can be used as an aid in the management of patients receiving cyclosporine.
Clinical Performance	Accuracy: (See Attachment B: Predicate Device Labeling, Section 11, Table 10.) The Syva Emit Package Insert provides Method Comparison Data from studies at four separate sites. Below our the results from one repre-sentative study comparing all 3 transplant types (heart, lung, kidney) to an HPLC Reference Method:	Accuracy: Method comparison of all transplant types to an HPLC reference method yielded the following results: Low range y = 0.99x + 8 r = 0.93, S.E.E. = 25.79;

Device Name	EMIT 2000 Cyclosporine Specific Assay (P920031)	CEDIA Cyclosporine Plus Assay (new device)
Clinical Performance, continued	Site 4: y=1.05 + 12; r = 0.96, S.E.E. = 25.33 Assay Range: 0 to 500 ng/mL. Within Imprecision: Percent CVs across 3 levels of cyclosporine concentrations were between 3.0% and 5.0%. Total Imprecision: Percent CVs across 3 levels of cyclosporine concentrations were between 4.5% and 10.5%.	High range y = 0.97x + 98 r = 0.970, S.E.E. = 80.65; Assay Range: Low 25 to 450 ng/mL. High 450 to 2000 ng/mL. Within Run Imprecision: Percent CVs across 5 levels of cyclosporine concentrations were between 3.0% and 8.0%. Total Imprecision: Percent CVs across 5 levels of cyclosporine concentrations were between 4.5% and 9.6% or S.D =7.4 for a control at 46 ng/mL.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 4 2002

Mr. Mark Hamilton Smith
Regulatory Specialist
Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538

Re: k023208
Trade/Device Name: CEDIA® Cyclosporine Plus Assay
Regulation Number: 21 CFR 862.1235
Regulation Name: Cyclosporine test system
Regulatory Class: Class II
Product Code: MKW; JIS
Dated: September 24, 2002
Received: September 25, 2002

Dear Mr. Smith:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INTENDED USE

510(K) Number (if known): ~~not known~~ K023308

Device Name: CEDIA® Cyclosporine Plus Assay

Indications for Use:

The CEDIA Cyclosporine Plus Assay is for the quantitative determination of cyclosporine in human whole blood using automated clinical chemistry analyzers as an aid in the management of therapy in kidney, liver, and heart transplants. The CEDIA Cyclosporine Calibrators are used to calibrate the CEDIA Cyclosporine Plus Assay in human whole blood.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023308

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over –the-Counter Use ___
(Per 21 CFR 801.109)