APR = 8 2011

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: K101752

Company/Contact person

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Date Prepared

May 17, 2010

Regulatory Declarations

Common / Usual Name	CEDIA® Multi-Drug OFT Calibrators
Trade/ Proprietary Name	Thermo CEDIA® Multi-Drug OFT Calibrators
Classification Regulation	21 CFR 862.3200
Device Class	Class II
Device Regulation Panel	Toxicology
Product Code	DKB

Intended use

The CEDIA® Multi-Drug OFT Calibrators are intended for use in the calibration of *d*-Amphetamine, Benzoylecgonine, Morphine and Phencyclidine (PCP) in human Oral Fluid when used with the CEDIA Amphetamine, Cocaine, Opiate, and Phencyclidine (PCP) OFT Assays on the MGC 240 analyzer. This *in vitro* diagnostic device is intended for clinical laboratory use only.

Legally marketed device to which equivalency is claimed

The CEDIA® Multi-Drug OFT Calibrators are substantially equivalent to the previously cleared CEDIA® DAU Multi-Drug Calibrators (K980853).

Description of the device

The CEDIA® Multi-Drug OFT Calibrators are liquid ready-to-use. They are prepared by spiking known quantities of Amphetamine, Benzoylecgonine, Morphine and PCP in to buffer matrix. The Cutoff Calibrator is used as a qualitative cutoff reference for distinguishing "positive" from "negative" samples. The concentration for each drug in the calibrators is listed in table below. Concentrations for each calibrator are confirmed by LC-MS/MS methodology.

Compound	Cutoff Calibrator (ng/mL)	High Calibrator (ng/mL)
Amphetamine	50	200
Benzoylecgonine	5	50
Morphine	10	80
Phencyclidine	1	20

Comparison of Technological Characteristics to the predicate device

Comparison	Subject Device CEDIA® Multi-Drug OFT Calibrators	Predicate Device CEDIA Multi-Drug DAU Calibrators (K980853)
Intended Use	The CEDIA® Multi-Drug OFT Calibrators are intended for use in the calibration of *d*-Amphetamine, Benzoylecgonine, Morphine and Phencyclidine (PCP) in human Oral Fluid when used with the CEDIA Amphetamine, Cocaine, Opiate, and Phencyclidine (PCP) OFT Assays on the MGC 240 analyzer. This *in vitro* diagnostic device is intended for clinical laboratory use only.	The CEDIA® DAU Multi-Drug Calibrators are intended for the calibration of qualitative and semi quantitative CEDIA® DAU Assays on automated clinical chemistry analyzers.
Analytes	Amphetamine Benzoylecgonine Morphine Phencyclidine (PCP)	Benzoylecgonine EDDP d-Methamphetamine Morphine Nitrazepam Phencyclidine (PCP) Secobarbital
Matrix	Buffer	Urine
Form	Liquid, ready to use	Liquid, ready to use
Calibrator levels	Negative Cutoff High	Primary Cutoff Secondary Cutoff Intermediate Calibrator High Calibrator
Storage Temperature	2-8°C	2-8°C

Conclusion

As summarized, the CEDIA® Multi-Drug OFT Calibrators are substantially equivalent to the CEDIA® Multi-Drug DAU Calibrators. 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
10903 New Hampshire Avenue
Silver Spring, MD 20993

Microgenics Corporation
Thermo Fisher Scientific Clinical Diagnostic Division
c/o Ms. Lisa Charter
Manager, Regulatory Affairs
46360 Fremont Blvd.
Fremont, CA 94538

APR 0 8 2011

Re: k101752
Trade Name: Thermo Scientific CEDIA Multi-Drug OFT Calibrators
Regulation Number: 21 CFR §862.3200
Regulation Name: Clinical Toxicology Calibrator
Regulatory Class: Class II
Product Codes: DKB
Dated: March 24, 2011
Received: March 28, 2011

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K101752

Device Name: Thermo Scientific CEDIA® Multi-Drug OFT Calibrators

Indication for Use:

The CEDIA® Multi-Drug OFT Calibrators are intended for use in the calibration of *d*-Amphetamine, Benzoylecgonine, Morphine and Phencyclidine (PCP) in human Oral Fluid when used with the CEDIA Amphetamine, Cocaine, Opiate, and Phencyclidine (PCP) OFT Assays on the MGC 240 analyzer. This *in vitro* diagnostic device is intended for clinical laboratory use only.

Prescription Use __X___ And/Or Over the Counter Use ____.
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101752