K012109

AUG 2 7 2001

microgenics

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: K01_____.

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

Submitter: Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538
phone: (510) 979-5150
fax: (510) 979-5455

Contact: Sherrie Rinne
Regulatory Specialist

Summary date: July 3, 2001

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

Name (trade): DRI ECSTASY URINE CALIBRATORS®

Name (usual): Ecstasy Urine Calibrators

Classification: Calibrator, Drug Specific; 21 CFR 862.3200, Class II, DJL (91)

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

DRI Ecstasy Urine Calibrators are substantially equivalent to DRI Multi-Drug Calibrators (Microgenics Corporation, Fremont, CA), cleared under premarket notification K983159

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

DRI Ecstasy Urine Calibrators are human urine-based and ready to use. They are prepared by spiking negative urine matrix with known quantities of 3,4-methylenedioxymethamphetamine (MDMA). The DRI Ecstasy 500 ng/mL Calibrator is used as the qualitative cutoff reference for distinguishing "positive" from "negative" samples.

The DRI Ecstasy Calibrators available are as follows"

250 ng/mL Calibrator
500 ng/mL Calibrator
750 ng/mL Calibrator
1000 ng/mL Calibrator

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

The DRI Ecstasy urine Calibrators are intended for the calibration of the DRI Ecstasy Immunoassay

Similarities to the Predicate(s) (21 CFR 807.92 (a)(6))
The DRI Ecstasy Urine Calibrators are similar in intended use, matrix, and performance to the DRI Multi-Drug Urine Calibrators.

Brief Discussion of Nonclinical/Clinical Data (21 CFR 807.92(b)(1, 2))
The DRI Ecstasy Urine Calibrators were evaluated via a series of traditional laboratory studies. These studies included the performance characteristics of precision, stability, and accuracy.

Performance Data - Conclusions (21 CFR 807.92 (b)(3))
The DRI Ecstasy Enzyme Immunoassay has been shown to be substantially equivalent to the predicate device, and safe and effective for its intended use.

The DRI Ecstasy urine calibrators were evaluated via a series of traditional laboratory studies. These studies included the performance characteristics of precision, stability, and accuracy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 7 2001

Ms. Sherrie Gene Rinne
Regulatory Specialist
Microgenics Corporation
46360 Fremont Boulevard
Fremont, CA 94538

Re: K012109
Trade/Device Name: DRI® Ecstasy Urine Calibrators
Regulation Number: 21 CFR 862.3200
Regulatory Class: II
Product Code: DLJ
Dated: July 3, 2001
Received: July 6, 2001

Dear Ms. Rinne:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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): K012109

Device Name: DRI® Ecstasy Urine Calibrators

Indications for Use:

The DRI® Ecstasy Urine Calibrators are intended for the calibration of the DRI Ecstasy Immunoassay.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over –the-Counter Use ___

Kesia Alexander for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K012109