K993755

DEC 21 1999

DADE BEHRING

SYVA COMPANY
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510 (k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92.

The assigned 510(k) number is:

The device is the Emit Calibrators/ Controls , Levels 0-5. The common or usual name is calibrators and/ or controls. The classification name is Clinical Toxicology Calibrator, 91 DKB.

The device is substantially equivalent to the following: Emit Calibrator Level O, Emit Calibrators A Level 1 and 2 and Emit Calibrators B Level 1 and 2.

The Emit Calibrators/Controls contain various combinations of the following drugs at varying concentrations: benzoyecgonine, lormetazepam, methadone, d-methamphetamine, methaqualone, morphine, 11-delta 9-THC-9-COOH, phencyclidine, propoxyphene and secobarbital. They are intended to be used with the following respective Emit II Plus assays for detecting: cocaine metabolite, benzodiazepines, methadone, amphetamines, methaqualone, opiates, cannabinoids, phencyclidine, propoxyphene and barbiturates.

The Emit Calibrators/ Controls are provided as ready-to–use liquids in a human urine matrix and they have characteristics common to a variety of commercially available calibrators and/or controls intended for use with assays for detecting drugs- of- abuse. The do not have any especially unique technical characteristics.

Where applicable, calibrators include concentrations of analytes that are required by the US Substance Abuse and Mental Health Services Administration (SAMHSA) for detecting drugs-of-abuse.

Nominal concentrations of each analyte are traceable to confirmation by GC/MS.

Studies have shown that none of the analytes cross react or otherwise interfere with the use of any of the Emit II Plus assays for which these products are intended and that the products are sufficiently stable for their intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 1999

Mr. Paul L. Rogers Jr.
Senior Manager, Regulatory Affairs
Syva Company
3403 Yerba Buena Road
San Jose, California 95135

Re: K993755
Trade Name: Emit® Calibrator/Control Level 0
Emit® Calibrator/Control Level 1
Emit® Calibrator/Control Level 2
Emit® Calibrator/Control Level 3
Emit® Calibrator/Control Level 4
Emit® Calibrator/Control Level 5
Regulatory Class: II
Product Code: DKB
Regulatory Class: I
Product Code: DIF
Dated: November 4, 1999
Received: November 5, 1999

Dear Mr. Wells:

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 (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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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

510(k) Number (If known): K993755

Device Name: Emit® Calibrator/Control Level 0
Emit® Calibrator/Control Level 1
Emit® Calibrator/Control Level 2
Emit® Calibrator/Control Level 3
Emit® Calibrator/Control Level 4
Emit® Calibrator/Control Level 5

Indications for Use:

The Emit Calibrator/Controls are used in the calibration of the Emit II Plus drugs-of-abuse assays. These standards may also be used as quality control materials based upon specified assay cutoff levels. The Emit Calibrator/Controls are used for the Emit II Plus Barbiturate, Benzodiazepine, Cannabinoid, Cocaine Metabolite, Methadone, Methaqualone, Mononclonal Amphetamine/Methamphetamine, Opiates, Phencyclidine, and Propoxyphene Assays.

Note:The above listed assays are currently in the process of being filed for 510(k) clearance.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993755