JUN 1 3 2002

Quantimetrix Corporation
2005 Manhattan Beach Boulevard
Redondo Beach, CA 90278-1205

TEL (800) 624-8380 or (310) 536-0006
FAX (800) 845-1834 or (310) 536-9977

510(K) SUMMARY

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

The assigned 510(k) number is: K021393

Proprietary Name:	Preciset® DAT Plus
Common Name:	Calibrators/Controls
Classification Name:	Calibrators, Drug Mixture
Medical specialty:	Clinical Toxicology
Product Code:	DKB
Device class:	2
Regulation No:	862.3200
Manufacturer:	Quantimetrix Corporation 2005 Manhattan Beach Boulevard Redondo Beach CA 90278 Phone: 310/536-0006 FAX: 310/536-9977
Contact Persons:	Gebhard Neyer, Ph.D., Director of R&D, 310-536-0006
Registration No:	2020715

The Quantimetrix Preciset® DAT Plus drug of abuse calibrator is supplied liquid in a glass bottle. It consists of drug-free human urine to which preservative, stabilizer and drugs of abuse have been added to achieve six distinct levels. The drugs added are: *metamphetamine, nordiazepam, barbiturates, cocaine/cocaine metabolites, methadone, morphine, phencyclidine, propoxyphene, cannabinoids*

Drug concentrations are determined using GC/MS.

The Quantimetrix calibrator is substantially equivalent to the currently marketed **Emit® Calibrators/controls** manufactured by **Syva Company.**
Both feature similar matrices, constituents and stability claims.

Intended Use

The Preciset DAT Plus calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

Performance Characteristics

Accelerated stability studies (25°C and 37°C) and real time studies were performed to validate the shelf life claim and the opened vial claim of the calibrators.
When tested with the Roche immunoassays (currently under development) the calibrators were found to perform well and to be sufficiently stable for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 1 3 2002

Dr. Gebhard Neyer
Director, Research & Development
Quantimetrix Corporation
2005 Manhattan Beach Boulevard
Redondo Beach, CA 90278-1205

Re: k021393
Trade/Device Name: Preciset® DAT Plus
Regulation Number: 21 CFR 862.3200
Regulation Name: Clinical toxicology calibrator
Regulatory Class: Class II
Product Code: DKB
Dated: May 1, 2002
Received: May 2, 2002

Dear Dr. Gebhard:

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

510(k) Number (if known): K021393

Device Name: Preciset® DAT Plus

Drug of Abuse Calibrators

Indications For Use:

The Preciset DAT Plus calibrators are designed for the calibration of the Roche assays for drugs of abuse in human urine on automated clinical chemistry analyzers.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021393

(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)