510(k) Summary-----Quest Diagnostics Urine Cocaine Metabolite EIA

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 K062929.

Date of Summary:
Sep. 15, 2006

DEC 18 2006

Correspondent:

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Product Name:
Common Name: Quest Diagnostics Urine Cocaine Metabolite EIA
Trade Name: Quest Diagnostics Urine Cocaine Metabolite EIA
Classification Number: 862.3250

Substantially Equivalent Device:
Product: DAT II Cocaine II
Manufactured by: Roche Diagnostics Cooperation
510(k) Number: K023281

Product Description:
Quest Diagnostics Urine Cocaine Metabolite EIA is a competitive homogenous enzyme immunoassay for the determination of cocaine metabolites in urine specimens.

Intended Use:
Quest Diagnostics Urine Cocaine Metabolite EIA is a competitive homogenous enzyme immunoassay for the qualitative detection of benzoylecgonine, the primary cocaine metabolite, in urine human specimens on automated clinical chemistry analyzers.

Comparison:
Quest Diagnostics Urine Cocaine Metabolite EIA, when used to qualitatively determine benzoylecgonine in urine specimens, is substantially equivalent to the DAT II Cocaine II assay manufactured by Roche Diagnostics Cooperation.

Comparison Performance Data:
Performance characteristic studies on precision, analytical sensitivity, interference and antibody cross-reactivity showed that the Quest Diagnostics Urine Cocaine Metabolite EIA is substantially equivalent to the DAT II Cocaine II assay.
Results screened from patient specimens with both the Quest Diagnostics Urine Cocaine Metabolite EIA and the DAT II Cocaine II assay also showed that the qualitative results from this two test systems are substantially equivalent when using GC/MS results as reference.

Conclusion:
Quest Diagnostics Urine Cocaine Metabolite EIA can be used to qualitatively screen benzoylecgonine, the primary cocaine metabolite, in human urine specimens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Liuming Yu
Quest Diagnostics
10101 Renner Boulevard
Lenexa, KS 66219

DEC 18 2006

Re: k062929
Trade/Device Name: Quest Diagnostics Urine Cocaine Metabolite EIA
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO
Dated: September 28, 2006
Received: September 28, 2006

Dear Mr. Yu:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K062929

Device Name: Quest Diagnostics Urine Cocaine Metabolite EIA

Indications For Use:

The Quest Diagnostics Urine Cocaine Metabolite EIA is intended for the qualitative detection of benzoylecgonine, the primary metabolite of cocaine, in human urine on automated clinical chemistry analyzers. It is a screen test with cutoffs of 300 ng/ml and 150 ng/ml of benzoylecgonine per ml of urine. This test is intended for laboratory use only. For in vitro diagnostic use.

The Quest Diagnostics Urine Cocaine Metabolite EIA provides only a preliminary result. Clinical consideration and professional judgment must be applied to any drug of abuse test result, particularly in evaluating a preliminary positive result. To obtain confirmed analytical results a more specific alternate chemical method is needed. Gas chromatography/mass spectroscopy (GC/MS) is the recommended confirmatory method.

The Quest Diagnostics Urine Cocaine Metabolite EIA Calibrators are intended for medical purposes and for use only with the Quest Diagnostics Urine Cocaine Metabolite EIA to establish points of reference that are used in the determination of values in the measurement of benzoylecgonine in urine.
The Quest Diagnostics Urine Cocaine Metabolite EIA Controls are intended for use as an assay quality control matrix to monitor the precision and accuracy of the laboratory testing procedures for benzoylecgonine.

Prescription Use ___✓___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K062929