510(k) Summary-----Quest Diagnostics Methamphetamine Micro-Plate EIA JUN 25 2008

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 K080381

Date of Summary: Apr. 9th, 2008

Correspondent:

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Product Name:

Common Name: Quest Diagnostics Methamphetamine Micro-Plate EIA
Trade Name: Quest Diagnostics Methamphetamine Micro-Plate EIA
Classification Number: 862.3610

Predicate Device:

Orasure Methamphetamine Intercept® Micro-Plate EIA

Product Description:

Quest Diagnostics Methamphetamine Micro-Plate EIA is a solid phase competitive enzyme immunoassay for the detection of Methamphetamine in oral fluid collected with the Orasure™ Oral Specimen Collection Device.

Intended Use:

Quest Diagnostics Methamphetamine Micro-Plate EIA is a competitive micro-immunoassay for the qualitative detection of Methamphetamines in oral fluid collected with the Orasure™ Oral Specimen Collection Device.

Comparison:

When used to qualitatively detect Methamphetamine in oral fluid specimens collected with the Orasure™ Oral Specimen Collection Device, the Quest Diagnostics Methamphetamine Micro-Plate EIA yields results in substantial agreement with the predicate device.

Comparison Performance Data:

Performance characteristic studies on precision, analytical sensitivity, interference and antibody cross-reactivity showed that the Quest Diagnostics Methamphetamine Micro-Plate EIA is in substantial agreement with the Orasure Methamphetamine Intercept® Micro-Plate EIA.

Results obtained from patient specimens showed that the qualitative results from the new assay are substantially equivalent to those obtained from the predicate device.

Conclusion:

The Quest Diagnostics Methamphetamine Micro-Plate EIA is substantially equivalent to the Orasure Methamphetamine Intercept® Micro-Plate EIA and can be used to qualitatively screen oral specimens collected with the Orasure™ Oral Specimen Collection Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Quest Diagnostics, Inc.
c/o Liuming Yu
Associate Director
10101 Renner Blvd.
Lenexa, KS 66219-9752

JUN 25 2008

Re: k080381/S001
Trade Name: Quest Diagnostics Methamphetamine Micro-Plate EIA
Regulation Number: 21 CFR 862.3610
Regulation Name: Methamphetamine Micro-Plate EIA
Regulatory Class: Class II
Product Codes: LAF
Dated: June 13, 2008
Received: June 17, 2008

Dear Liuming 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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
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 Statement

510(k) Number (if known) K 080381

Device Name: Quest Diagnostics Methamphetamine Micro-Plate EIA

Indications for Use

The Quest Diagnostics Methamphetamine Micro-Plate EIA is intended for the qualitative detection of Methamphetamine in oral fluid collected with the Orasure™ Oral Specimen Collection Device. It is a screen test with a cutoff of 40 ng/ml.

The Quest Diagnostics Methamphetamine Micro-Plate 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 Methamphetamine Micro-Plate EIA Calibrators are intended for medical purposes and for use only with the Quest Diagnostics Methamphetamine Micro-Plate EIA to establish points of reference that are used in the determination of values in the measurement of methamphetamine in oral fluid samples collected with OraSure™ Oral Specimen Collection Device.

The Quest Diagnostics Methamphetamine Micro-Plate EIA Controls are intended for use as an assay quality control matrix to monitor the precision and accuracy of the laboratory testing procedures for methamphetamine in oral fluid samples collected with OraSure™ Oral Specimen Collection Device.

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

Carol C. Benson
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

K080381