JAN 2 3 2012 K112808

Omega Laboratories, Inc.
510(k) Summary
Omega Hair Drug Screening Assay for Cocaine and Cocaine Metabolites

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

510(k) Number:

Date of Summary: September 23, 2011

Applicant:

William R. Corl
Vice President of Operations

Omega Laboratories, Inc.
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Mogadore, OH 44260
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Correspondent:

Name: Robert J Bard, JD

Address: Omega Laboratories
400 North Cleveland, Mogadore, OH 44260

Phone Number: 248-573-5040

E-mail rbard@reglaw.net

Product Name:

Trade Name: Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites

Common Name: Hair Drug Screening Assay Cocaine and Cocaine Metabolites

Regulation Number: CFR 862.3250 (ProCode DIO)

Classification Name: Enzyme immunoassay, Cocaine and Cocaine Metabolites test System

Classification Panel: 91 (Toxicology)

Predicate Device: Quest Diagnostics HairCheck-DT (Cocaine) k023626;

Product Description: The Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites, is a test system using ELISA reagents and micro-plate reader for the qualitative detection of Cocaine and Cocaine Metabolites in hair samples at or above 500 pg/mg.

Indication for Use: The Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites (Cocaine) is a laboratory developed test that is intended to be used for the determination of the presence of Cocaine in human hair from the head. The Omega Laboratories Hair Drug Screening Assay Cocaine utilizes the International Diagnostics Systems Corp. One-Step enzyme linked immunosorbent assay (ELISA) for Cocaine Testing Kit, for the qualitative detection of Cocaine at or above 500 pg/mg of hair for the purpose of identifying the use of Cocaine. To confirm a screen positive result, a more specific alternate chemical method, such as Gas Chromatography/Mass Spectrometry

(GC/MS) operating in the selected ion monitoring (SIM) mode is the preferred method with deuterated internal standards. Professional judgment should be applied to any drug of abuse test result, particularly when presumptive positive results are obtained.

This laboratory developed test is intended exclusively for in-house laboratory use only and is not intended for sale to anyone. Omega offers this laboratory developed test as a service to its clients.

Comparison:

When used to qualitatively detect Cocaine and Cocaine Metabolites in head hair specimens collected with the Omega Specimen Collection Device, the Omega assays yield results in substantial agreement with the predicate device.

Comparison Performance Data:

Performance characteristic studies were conducted for

Detection Limits and Reportable Range

Precision

Agreement

Cosmetic Treatment

Cross reactivity

Environmental Contamination

Calibrator and Control

Extraction Recovery

Shipping Study

Stability of Hair Sample

All performance studies demonstrated that the Omega assay is in substantial agreement with the predicate products.

Results obtained from donor specimens showed that the qualitative results from the new assays are substantially equivalent to those obtained from the predicate devices.

Conclusion:

The Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites is substantially equivalent to the Quest Diagnostics HairCheck-DT (Cocaine) k023626.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Omega Laboratories, Inc.
c/o Mr. Robert Bard
400 N. Cleveland Avenue
Mogadore, OH 44260

JAN 23 2012

Re: k112808
Trade Name: Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites
Regulation Number: 21 CFR §862.3250
Regulation Name: Cocaine and Cocaine Metabolite Test System
Regulatory Class: Class II
Product Codes: DIO
Dated: December 17, 2011
Received: December 19, 2011

Dear Mr. Bard:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

K112808

Device Name: Omega Laboratories Hair Drug Screening Assay for Cocaine and Cocaine Metabolites

Indication for Use:

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Prescription Use _____ (21 CFR Part 801 Subpart D)	and/or	Over the Counter Use ___x___ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K112808