DEC 1 3 2011

Omega Laboratories, Inc.
510(k) Summary
Omega Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone

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: K103161

Date of Summary: June 14, 2011

Applicant:

William R. Cori
Vice President of Operations

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Mogadore, OH 44260
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Correspondent:

Name: Robert J Bard, JD

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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 Opiates, Oxycodone and Hydrocodone

Common Name: Hair Drug Screening Assay Opiates

Regulation Number: CFR 862.3650 (ProCode DJG)

Predicate Device: Quest Diagnostics HairCheck-DT (Opiates) k042725; RadipOne –OXY Test (American Bio Medica Corporation) (Oxycodone) K014101

Product Description: The Omega Laboratories Hair Drug Screening Assays for Opiates, Oxycodone and Hydrocodone are test systems using ELISA reagents and micro-plate reader for the qualitative detection of Opiates, Oxycodone and Hydrocodone in hair samples at or above 300 pg/mg.

Indication for Use: The Omega Laboratories Hair Drug Screening Assays are test systems that utilize ELISA assays for the qualitative detection of morphine and related opiates (calibrated with morphine) and oxycodone and hydrocodone (calibrated with oxycodone) at or above 300 pg/mg in head hair samples.

The Omega Laboratories Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone provide only preliminary analytical test results. A more specific alternate chemical method must be used in order to obtain a confirmed result. Gas Chromatograph – Mass Spectrometry operating in the selected ion monitoring (SIM) mode or GC/MS/MS in selected reaction mode (SRM) is the preferred method with deuterated internal standards.

Comparison: When used to qualitatively detect Opiates, Oxycodone and Hydrocodone 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 on precision, analytical sensitivity, interference and antibody cross-reactivity showed that the Omega assays are in substantial agreement with the Quest Diagnostic and American Bio Medica 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 Opiates, Oxycodone and Hydrocodone is substantially equivalent to the Quest Diagnostics HairCheck-DT (Opiates) k042725; RadipOne –OXY Test (American Bio Medica Corporation) (Oxycodone) K014101 and can be used to qualitatively screen hair specimens collected with the Omega Specimen Collection Device for Opiates, Oxycodone and Hydrocodone.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

DEC 13 2011

OMEGA Laboratories
c/o HealthCare Technologies Consultants
c/o Robert Bard
P. O. Box 506
South Lyon, MI 48178

Re: k103161
Trade Name: Omega Laboratories Hair Drug Screening Assays for Opiates, Oxycodone and Hydrocodone
Regulation Number: 21 CFR §862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Codes: DJG
Dated: November 28, 2011
Received: November 30, 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

Device Name: Omega Laboratories Hair Drug Screening Assays for Opiates, Oxycodone and Hydrocodone.

Indication for Use:

The Omega Laboratories Hair Drug Screening Assays are test systems that utilize ELISA assays for the qualitative detection of morphine and related opiates (calibrated with morphine) and oxycodone and hydrocodone (calibrated with oxycodone) at or above 300 pg/mg in head hair samples.

The Omega Laboratories Hair Drug Screening Assay for Opiates, Oxycodone and Hydrocodone provide only preliminary analytical test results. A more specific alternate chemical method must be used in order to obtain a confirmed result. Gas Chromatograph – Mass Spectrometry operating in the selected ion monitoring (SIM) mode or GC/MS/MS in selected reaction mode (SRM) is the preferred method with deuterated internal standards. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

These laboratory developed tests are intended exclusively for in-house professional use only and are not intended for sale to anyone. Omega offers these laboratory developed tests as services to its clients.

Prescription Use _____	And/Or	Over the Counter Use _X_
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

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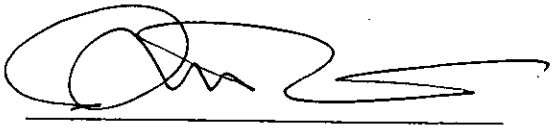
Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



Division Sign-Off

Office of In Vitro Diagnostic Device

Evaluation and Safety

510(k) K103161