510(k) Summary

DEC 5 2012

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: K122759

Date of Summary: December 4, 2012

Applicant:

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Product Name:

Trade Name: Omega Laboratories Hair Drug Screening Assay Carboxy-THC (THCA)

Common Name: Hair Drug Screening Assay for THCA

Regulation Number: 21 CFR 862.3870 (ProCode LDJ)

Classification Name: Enzyme immunoassay, Cannabinoids

Classification Panel: 91 (Toxicology)

Predicate Device: Psychemedics Microplate EIA for Cannabinoids in Hair K111929

Product Description: The test consists of two parts; a pre-analytical proprietary and patent pending hair treatment procedure (to remove THCA from the solid hair matrix to a measurable liquid matrix), and the screening assay. The screening assay is an Enzyme-Linked ImmunoSorbent Assay (ELISA).

Sample is added to a well of the micro strip plate and enzyme conjugate is added, followed by incubation. During this phase, the enzyme-labeled drug conjugate competes with drug in the sample for a limited number of binding sites on the rabbit antibody-coated micro wells. The two bind in proportion to their concentrations. A wash solution is applied to remove any unbound materials. Enzyme substrate solution containing a chromagen is added. The reaction is stopped with an acid and the absorbance is read using a plate reader at 450 nm. A background reading is also taken at 630 nm. Color intensity is inversely proportional to the amount of drug present in the

sample.

Indication for Use:

The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC (THCA) is an in vitro diagnostic test that is intended to be used for the determination of the presence of cannabinoids in human head and body hair samples. The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC utilizes the International Diagnostics Systems Corp. enzyme linked immunosorbent assay (ELISA) for THC Metabolite Testing Kit, for the qualitative detection of THCA at or above 1 pg/mg of hair for the purpose of identifying the use of cannabinoids.

The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC provides only preliminary analytical test results and must be used in combination with a more specific alternate chemical method 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 used as the confirmation method, along with deuterated internal standards.

Omega plans to perform this test at one site. Omega has not performed an evaluation of reproducibility at different laboratories.

Comparison:

See Appendix A

Performance Data:

Performance characteristic studies were conducted for

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.

LIMITATIONS: Performance of this assay in specific user populations has not been characterized. The donor population in the historical data was not fully characterized. Interpretation of results must take into account that drug concentrations detected in hair from a single individual can vary extensively depending on the site of collection. Positive screening results only indicate the presumptive presence of THCA, and require a more specific alternate chemical method, such as Gas Chromatography/Mass Spectrometry (GC/MS/MS) to confirm the result. A negative screening result does not necessarily rule out the possibility of THC use, i.e., time of collection, frequency of use, mode of ingestion, dosage used, hair types and other factors may influence results. It will not be possible to document all possible effects due to treatments such as bleaching, straightening and dying. There is a possibility that other substances and/or factors not evaluated in the interference studies may interfere with the test and cause false results that cannot be confirmed by mass spectrometry, e.g. technical or procedural errors.

PRECISION : Intra-assay precision studies were performed using 10 replicates of negative hair samples spiked to the following concentrations of THCA: zero drug, -75%, -50%, -25% below the cutoff, and +25%, +50%, +75% and+100% above the cutoff. All samples were treated and analyzed in the same manner as donor hair samples and measured in one run.

THCA Intra-Assay Precision Studies

Drug	Concentration of Sample (pg/mg)	Number of Replicates	Results # Negative	Results # Positive
THCA	0	10	10	0
THCA	0.25	10	10	0
THCA	0.50	10	10	0
THCA	0.75	10	10	0
THCA	1.25	10	0	10
THCA	1.50	10	0	10
THCA	1.75	10	0	10
THCA	2.00	10	0	10

Inter-assay precision studies were performed using negative hair samples spiked to the following concentrations of THCA: zero drug, -75%, -50%, -25% below the cutoff, and +25%, +50%, +75% and+100% above the cutoff. All samples were treated and analyzed in the same manner as donor hair samples. Ten replicates of these were prepared and analyzed over 20 non-consecutive.

Table 16: THCA Inter-Assay Precision Studies (CO=1 pg/mg)

Drug	Concentration of Sample (pg/mg)	Number of Replicates	Results # Negative	Results # Positive
THCA	0	200	200	0
THCA	0.25	200	200	0
THCA	0.50	200	200	0
THCA	0.75	200	200	0
THCA	1.25	200	0	200
THCA	1.50	200	0	200
THCA	1.75	200	0	200
THCA	2.00	200	0	200

CROSSREACTIVITY The Crossreactivity Study demonstrated that the presence of the structurally similar compounds (-) 11-nor-9-Carboxy-delta9-THC, (+/-) 11-nor-9-Carboxy-delta9-THC, (-) 11-nor-9-Carboxy-delta8-THC, (-)-delta8-THC, (-)-delta9-THC, (+/-) 11-Hydroxy-delta9-THC, Cannabinol, Cannabidiol, Nabilone, and JWH-018 may contribute to a THC Metabolite positive ELISA result when utilizing this protocol. Since a GC/MS/MS confirmation is performed on all presumptive positive screening results, these compounds will not confirm as a positive result report. All of the other compounds studied did not demonstrate any interference with the protocol.

Table 22. Cross reactivity of the Omega Laboratories, Inc. THC Metabolite ELISA with Structurally Similar Compounds

Compound	Approximate Concentration of Compound (pg/mg) Equivalent to 1pg/mg (-) 11-nor-9-Carboxy-delta9-THC Cutoff Control (n=3)	Percent Crossreactivity (%)
(-) 11-nor-9-Carboxy-delta9-THC	1.0	100.0
(+/-) 11-nor-9-Carboxy-delta9-THC	1.0	100.0
(-) 11-nor-9-Carboxy-delta8-THC	0.45	222.2
(-)-delta8-THC	60.0	1.7
(-)-delta9-THC	50.0	2.0
(+/-) 11-Hydroxy-delta9-THC	5.0	22.2
Cannabinol	70.0	1.4
Cannabidiol	3000	0.03
Nabilone	>400000	<0.01
JWH-018	>40000	<0.01

CALIBRATOR AND CONTROL: The Omega Laboratories, Inc. ELISA Screening Protocol utilizes in-house prepared calibrator and control solutions. The study demonstrated the validation and stability of these solutions along with the traceability to NIST standards.

The study demonstrated the stability of THCA in methanol for a period of six months when stored refrigerated in an amber bottle. The quantitative value after a six month period as compared to a freshly prepared solution is within 10% of the target value of 2.5 pg/mg. This validates the six months expiration date for the THCA Stock Solution.

STABILITY: Stability Studies determined whether there are any adverse effects on the level of THCA contained in a hair sample when it is placed in storage for an extended period of time. Two storage time points were used (1 year and 2.5 years)

The Stability Study demonstrated that the mean variance on the concentration of THCA in hair samples when stored for a 1 year period was -30.7%.

COSMETIC TREATMENT: Numerous studies have demonstrated that the use of cosmetic treatments can reduce the amount of drugs and metabolites detected in hair specimens (see attached references). This effect is completely dependent upon the nature of the hair specimen and the treatment used, and is

independent of the method of analysis. This study demonstrates that the Omega Laboratories, Inc. ELISA THCA Screening Protocol is not an exception to this phenomenon.

Study results found bleach and relaxer treatments had the greatest effect on positive samples resulting in an average decrease in THCA concentration of 19%. This was followed by dying and permanents resulting in an average decrease in THCA concentration of 16% and 14%, respectively. The mean effect of shampoos was 6%.

This effect was similar for negative samples. The quantitative values before and after all treatments where data was available averaged -19% (n=8).

Conclusion: The Omega Laboratories Hair Drug Screening Assay for THCA is substantially equivalent to the predicate Psychemedics Corp Microplate EIA for Cannabinoids in Hair (K111929).

Appendix A: Comparison of Omega Laboratories THCA Assay vs Psychemedics Microplate EIA for Cannabinoids in Hair

Comparison Element - Similarities	**Hair Drug Screening Assay for THCA (Subject devices)**	**Psychemedics Microplate EIA for Cannabinoids in Hair (K111929) Primary Predicate**
Laboratory	Omega Laboratories, Inc.	Psychemedics Corp.
Indication for/ Intended Use	The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC (THCA) is an in vitro diagnostic test that is intended to be used for the determination of the presence of cannabinoids in human head and body hair samples. The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC utilizes the International Diagnostics Systems Corp. enzyme linked immunosorbent assay (ELISA) for THC Metabolite Testing Kit, for the qualitative detection of THCA at or above 1 pg/mg of hair for the purpose of identifying the use of cannabinoids. The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC provides only preliminary analytical test results and must be used in combination with a more specific alternate chemical method 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 used as the confirmation method, along with deuterated internal standards. Omega plans to perform this test at one site. Omega has not performed an evaluation of reproducibility at different laboratories..	The Psychemedics Microplate EIA for Cannabinoids in Hair is an enzyme immunoassay (EIA) for the preliminary qualitative detection of cannabinoids in human head and body hair samples using a 11-nor-9-Carboxy- Δ9-THC calibrator at 10 pg/10 mg hair cutoff for the purpose of identifying marijuana use. This is an *in vitro* diagnostic device 2 intended exclusively for Psychemedics use only and is not intended for sale to anyone. The Psychemedics Chemiluminscent Microplate EIA for Cannabinoids assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry/Mass Spectrometry (GC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.

Appendix A: Comparison of Omega Laboratories THCA Assay vs Psychemedics Microplate EIA for Cannabinoids in Hair

Comparison Element - Similarities	**Hair Drug Screening Assay for THCA (Subject devices)**	**Psychemedics Microplate EIA for Cannabinoids in Hair (K111929) Primary Predicate**
Micro-plate	International Diagnostics Systems Corp Forensic Human Drugs of Abuse HTC Metabolite ELISA for Hair Test IDS -4800-OM	Psychemedics Corp. Chemiluminscent Microplate EIA for Cannabinoids assay.
Method of Measurement	Microplate reader. Read at 450 nm	Microplate reader. Read at 450 nm
Matrix	Head and body hair	Head and body hair
Cutoff concentration	1 pg THCA /mg hair	10 pg THCA /10 mg hair
Assay Principal	Enzyme linked immunosorbent assay (ELISA)	EIA (Qualitative chemiluminescent enzyme immunoassay EIA)
Extraction Method	Utilized acid-methanol vs methanol alone to facilitate extraction of THCA from hair. Proprietary and patent pending method of pulverizing hair vs cutting the hair into small segments prior to acid-methanol extraction. This improved extraction times without loss of efficiency	Proprietary extraction method

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

December 5, 2012

Omega Laboratories, Inc.
c/o Robert J. Bard
400 North Cleveland
Mogadore, Ohio 44260

Re: k122759
Trade/Device Name: Omega Laboratories Hair Drug Screening Assay Carboxy – THC (THCA)
Regulation Number: 21 CFR §862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ
Dated: October 4, 2012
Received: October 5, 2012

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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson for

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

Enclosure

Indications for Use

510(k) Number (if known): k122759

Device Name: Omega Laboratories Hair Drug Screening Assay for Carboxy-THC (THCA)

Indications for Use:

The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC (THCA) is an in vitro diagnostic that is intended to be used for the determination of the presence of cannabinoids in human head and body hair samples. The Omega Laboratories Hair Drug Screening Assay for Carboxy-THC utilizes the International Diagnostic Systems Corp. enzyme linked immunosorbant assay (ELISA) for THC Metabolite Testing Kit, for the qualitative detection of THCA at or above 1 pg/mg of hair for the purpose of identifying the use of cannabinoids.

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Omega plans to perform this test at one site. Omega has not performed an evaluation of reproducibility at different laboratories.

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 Diagnostics and Radiological Health (OIR)

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k) K122759