MAY 12 2010

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990 and 21 CFR 807.92

The assigned 510(k) number is: K093114

COMPANY/CONTACT PERSON

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DATE PREPARED

May 10, 2010

DEVICE NAME

Trade Name:	Thermo Scientific DRI ® Amphetamines Assay
Common Name:	DRI ® Amphetamines Assay
Device Classification:	Amphetamine test system, Methamphetamine Test System
Regulation number:	21 CFR 862.3100, 21 CFR 862.3610
Product Code:	DKZ, LAF

INTENDED USE

The DRI® Amphetamines Assay is intended for the qualitative or semi-quantitative determination of amphetamine and methamphetamine in human urine. The assay has cutoff levels of 500 and 1000 ng/mL. The assay provides a simple and rapid analytical screening procedure for detecting amphetamine and methamphetamine in urine on automated clinical analyzers. The assay is calibrated with methamphetamine.

This 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 (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

SUBSTANTIALLY EQUIVILANT PREDICATE DEVICE

Thermo Scientific DRI® Amphetamines Assay is substantially equivalent to the previously cleared CEDIA® DAU Amphetamines Assay (k943993).

SUMMARY AND EXPLANATION OF THE TEST

Amphetamines are synthetic derivatives of ephedrine. The most common amphetamines include d-amphetamine, d-methamphetamine, and d, l-amphetamine. They act as stimulants for the central nervous system. Amphetamine is the most sympathomimetic amine. When amphetamine is ingested, it is either

rapidly deactivated in the liver or excreted unchanged into the urine. Other ephedrine derivatives such as methamphetamine can be metabolized and excreted in urine as amphetamine.

The DRI Amphetamines Assay is a liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies, which can detect amphetamine and/or methamphetamine in urine with minimal cross-reactivity to various over-the-counter structurally unrelated compounds. The assay is based on the competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug labeled with G6PDH and causes a decrease in enzyme activity. In the presence of free drug, the free drug occupies the antibody binding sites, allowing the drug-labeled G6PDH to interact with the substrate, resulting in enzyme activity. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Comparison	CEDIA® Amphetamines Assay (K943993)	Thermo Scientific DRI® Amphetamines Assay (K093114)
Intended Use	The CEDIA® Amphetamines assay is an in-vitro diagnostic medical device intended for the qualitative and semi quantitative assay of amphetamines in human urine. The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.1 Clinical consideration and professional judgment should be applied to any drug of abuse test result particularly when preliminary positive results are used.	The DRI® Amphetamines Assay is intended for the qualitative or semi-quantitative determination of amphetamine and methamphetamine in human urine. The assay has cutoff levels of 500 and 1000 ng/mL. The assay provides a simple and rapid analytical screening procedure for detecting amphetamine and methamphetamine in urine on automated clinical analyzers. The assay is calibrated with methamphetamine. This 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 (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.
Test Principle	The CEDIA Amphetamines assay uses recombinant DNA technology (US Patent No. 4708929) to produce a unique homogeneous enzyme immunoassay system.7 This assay is based on the bacterial enzyme ß-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically. In the assay, drug in the sample competes with drug conjugated to one inactive fragment of	The DRI Amphetamines Assay is a liquid ready-to-use homogeneous enzyme immunoassay. The assay uses specific antibodies, which can detect amphetamine and/or methamphetamine in urine with minimal cross-reactivity to various over-the-counter structurally unrelated compounds. The assay is based on the competition of an enzyme glucose-6-phosphate dehydrogenase (G6PDH) labeled drug and the drug from the urine sample for a fixed amount of specific antibody binding sites. In the absence of free drug from the sample, the specific antibody binds the drug labeled with

	ß-galactosidase for antibody binding site. If drug is present in the sample, it binds to antibody, leaving the inactive enzyme fragments free to form active enzyme. If drug is not present in the sample, antibody binds to drug conjugated on the inactive fragment, inhibiting the reassociation of inactive ß-galactosidase fragments, and no active enzyme will be formed. The amount of active enzyme formed and resultant absorbance change are proportional to the amount of drug present in the sample.	G6PDH and causes a decrease in enzyme activity. In the presence of free drug, the free drug occupies the antibody binding sites, allowing the drug-labeled G6PDH to interact with the substrate, resulting in enzyme activity. This phenomenon creates a direct relationship between drug concentration in urine and the enzyme activity. The enzyme activity is determined spectrophotometrically at 340 nm by measuring its ability to convert nicotinamide adenine dinucleotide (NAD) to NADH.
Cutoff	500 and 1000 ng/mL	500 and 1000 ng/mL
Matrix	Human Urine	Human Urine
Reagents	Lyophilized Two reagent assay (R1 and R2)	Liquid Ready-to-Use Two reagent assay (R1 and R2)
Calibrators	Liquid ready-to-use (0, 500, 1000, 3000, 5000 ng/mL)	Liquid ready-to-use (0, 500, 1000, 1500, 2000 ng/mL)
Controls	Liquid ready-to-use (375 and 625, 750 and 1250 ng/mL)	Liquid ready-to-use (375 and 625, 750 and 1250 ng/mL)
Storage Condition	2-8°C	2-8°C

PERFORMANCE TESTING SUMMARY

Precision and Accuracy

Samples spiked with d-amphetamine and d-methamphetamine were tested for precision in qualitative and semi-quantitative assays following a randomized CLSI protocol. The precision study met the design specifications in both the qualitative and semi-quantitative assays. In the qualitative study, all negative samples recovered as negative and all positive samples recovered as positive. In the semi-quantitative study, the within run %CV for was less than or equal to 6.2% and the total run %CV was less than or equal to 6.9%.

Method Comparison

Samples were tested by DRI qualitative and semi-quantitative assay and compared to GC/MS. The method comparison exhibited results greater than 96% total agreement between the DRI methods and GC/MS for both qualitative and semi-quantitative assays. Discordant results were obtained when the assay was used to detect amphetamine and methamphetamine analytes individually. The assay detects the presence of both amphetamine and methamphetamine analytes with 100% cross reactivity to both drugs. Therefore samples tested for one analyte may appear discordant due to the presence of the other analyte.

The method comparison results meet the design input specifications.

Dilution Recovery

Samples were tested to demonstrate linearity throughout the assay range. Results showed that recovery was less than ±4% error of the expected value for levels tested from 0 to 2000 ng/mL. The results met the design input specification for levels tested throughout the assay range, and the assay dilutes in a linear fashion.

On-Board Open Vial reagent Stability

Uncapped reagents were stored in an analyzer and all calibrators and controls were tested in qualitative and semi-quantitative assay. Reagents stored on the analyzer are stable for a minimum of 60 days.

CONCLUSION

As summarized, the Thermo Scientific DRI® Amphetamines Assay is substantially equivalent to the CEDIA® Amphetamines Assay. Substantial equivalence has been demonstrated through performance testing to verify that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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MAY 12 2010

Re: k093114
Trade/Device Name: DRI Amphetamines Assay
Regulation Number: 21 CFR 862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ, LAF
Dated: May 7, 2010
Received: May 10, 2010

Dear Ms. Takkele:

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 class II (Special Controls), 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). 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

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 C. Harper, Ph.D.
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

510(k) Number (if known): K093114

Device Name: DRI® Amphetamines Assay

Indication for Use:

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This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a con firmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (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) K093114