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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: K100144

COMPANY/CONTACT PERSON

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DATE PREPARED

January 12, 2011

DEVICE NAME

Trade Name:	Thermo Scientific QMS® Everolimus Assay
	Thermo Scientific QMS® Everolimus Calibrators
	Thermo Scientific QMS® Everolimus Controls
Common Name:	QMS® Everolimus Assay System
Device Classification:	Sirolimus test system
Regulation number:	21 CFR 862.3840
Product Code:	NRP

INTENDED USE

The QMS® Everolimus assay is intended for the quantitative determination of everolimus, the active ingredient of Zortress®, in human whole blood on automated clinical chemistry analyzers. The results obtained are used as an aid in the management of kidney transplant patients receiving Everolimus therapy. This *in vitro* diagnostic device is intended for clinical laboratory use only.

The QMS® Everolimus Calibrators set is intended for use in calibration of the QMS® Everolimus Assay.

The QMS® Everolimus Controls set is intended for use in quality control of the QMS® Everolimus Assay.

SUBSTANTIALLY EQUIVILANT PREDICATE DEVICE

Thermo Scientific QMS® Everolimus Assay is substantially equivalent to the previously cleared CEDIA® Sirolimus Assay (K034069).

PRINCIPLE OF THE ASSAY

The QMS® Everolimus Assay system is a homogeneous assay utilizing particle agglutination technology and competitive binding principles.

In particle agglutination assays, the degree of agglutination (detected by optical method at 700nm) is inversely proportional to the quantity of free drug in the reaction well. Hence, if no drug is present in the sample, the antibodies in the QMS® Everolimus Antibody Reagent (R1) will bind only to the bound drug on the particle which will cause it to agglutinate and will result in higher absorbance. If increased amount of competing drug is present in the sample, this will result in decreased binding of bound drug by the antibody, resulting in a relative decrease in particle agglutination. This in turn results in lower absorbance.

The precise relationship between particle agglutination and concentration of the unlabeled drug in the sample is established by measuring the absorbance values of calibrators with known concentration of the drug. The absorbance of unknown samples can be interpolated from the absorbance values of the calibration curve and the concentration of the drug present in the sample can be calculated.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Comparison	**Predicate Device** **CEDIA® Sirolimus Assay (K034069)**	**Thermo Scientific** **QMS® Everolimus Assay**
Intended Use	The CEDIA® Sirolimus Assay is an in vitro diagnostic medical device intended for the quantitative determination of sirolimus in human whole blood using automated clinical chemistry analyzers as an aid in the management of sirolimus therapy in renal transplant patients taking sirolimus.	The QMS® Everolimus Assay is intended for the quantitative determination of everolimus, the active ingredient of Certican®, in human whole blood on automated clinical chemistry analyzers. The results obtained are used as an aid in the management of kidney transplant patients receiving Everolimus therapy.
Test Principle	The CEDIA® Sirolimus Assay uses recombinant DNA technology (US Patent No. 4708929) to produce a unique homogenous enzyme immunoassay system.16 The assay is based on the enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously reassociate to form fully active enzymes that, in assay format, cleave a substrate, generating a color change that can be measured spectrophotometrically. In the assay, analyte in the specimen competes with analyte conjugated to one inactive fragment of β-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragments free to form active enzymes. If analyte is not present in the sample, antibody binds to analyte conjugated to the inactive fragment, inhibiting the reassociation of inactive β-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of analyte present in the sample.	The QMS® Everolimus Assay system is a homogeneous assay utilizing particle agglutination technology and competitive binding principles. In particle agglutination assays, the degree of agglutination (detected by optical method at 700nm) is inversely proportional to the quantity of free drug in the reaction well. Hence, if no drug is present in the sample, the antibodies in the QMS® Everolimus Antibody Reagent (R1) will bind only to the bound drug on the particle which will cause it to agglutinate and will result in higher absorbance. If increased amount of competing drug is present in the sample, this will result in decreased binding of bound drug by the antibody, resulting in a relative decrease in particle agglutination. This in turn results in lower absorbance. The precise relationship between particle agglutination and concentration of the unlabeled drug in the sample is established by measuring the absorbance values of calibrators with known concentration of the drug. The absorbance of unknown samples can be interpolated from the absorbance values of the calibration curve and the concentration of the drug present in the sample can be calculated.

Sample Matrix	Human Whole Blood	Human Whole Blood
gents	Two Lyophilized reagents (R1 and R2) One Liquid Ready-to-Use Reagent (Precipitation reagent)	Three Liquid Ready-to-Use reagents (R1,R2 and Precipitation reagent)
Reagent storage Condition	2-8°C	2-8°C
Calibrators	Lyophilized (0 and 30 ng/mL)	Liquid ready-to-use (0, 1.5, 3.0, 6.0,12.0 and 20.0 ng/mL)
Controls	Lyophilized (Low, Medium, High)	Liquid ready-to-use (Low, Medium, High)
Calibrator and Control Storage Condition	5°C ±3°C (2-8°C)	-20°C ± 5°C (15-25°C)
Calibrator Traceability	Traceable to purified sirolimus	Traceable to calibration based on minimization of bias between the QMS assay and an LCMSMS assay for a specified adult renal transplant sample set.

PERFORMANCE TESTING SUMMARY

Functional Sensitivity (LOQ)
Functional Sensitivity determines the lowest concentration which results at a C.V. of 20% that has been measured over an extended period. The LOQ claim will be 2.0 ng/mL.

Precision and Accuracy
Everolimus samples tested for precision following a CLSI protocol. In the study, the total run %CV was less than or equal to 15.0%.

Method Comparison
Samples were tested in the Everolimus Assay and compared to LC/MS. The method comparison exhibited correlated well with LC/MS as follows:
System 1 = 0.93x + 0.03 R2 = 0.94
System 2 = 1.00x - 0.08 R2 = 0.95

Dilution Recovery
Samples were tested to demonstrate linearity throughout the assay range. Results showed that the assay performs 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 the assay. Reagents stored on the analyzer are stable for up to 30 days.

CONCLUSION

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

7. Brignol N, McMahon LM, Luo S, et al. High-throughput semi-automated 96-well liquid/liquid extraction and liquid chromatography/mass spectrometric analysis of everolimus (RAD001) and cyclosporine A (CsA) in whole blood. Rapid Commun Mass Spectrom 2002; 15: 1-10.
8. Streit F, Armstrong VW, Oellerich M, et al. Rapid liquid chromatography-tandem mass spectrometry routine method for simultaneous determination of sirolimus, everolimus, tacrolimus, and cyclosporine A in whole blood. Clin Chem 2002; 48 (6): 955-958.
9. Bablok W, Passing H, Bender R, Schneider B. A general regression procedure for method transformation. Application of linear regression procedures for method comparison studies in clinical chemistry. Part III *J Clin Chem Clin Biochem* 1988; 26 (11): 783-790.
10. Tholen DW, Kallner A, Kennedy JW, et al. *Evaluation* of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition (EP5-A2). Clinical and Laboratory Standards Institute (CLSI), Wayne, PA, 2004.
11. McEnroe RJ, Burritt MF, Powers DM, et al. Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition (EP7-A2). Clinical and Laboratory Standards Institute (CLSI), Wayne, PA, 2005.

TRADEMARKS

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 11 2011

Microgenics Corporation
c/o Ms. Lisa Charter
Manager, Regulatory Affairs
46360 Fremont Blvd.
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Re: k100144
Trade Name: Thermo Scientific QMS® Everolimus Reagents, Thermo Scientific QMS® Calibrators and Thermo Scientific QMS® Controls
Regulation Number: 21 CFR 862.3840
Regulation Name: Sirolimus test system.
Regulatory Class: Class II
Product Codes: OUF, DLJ, LAS
Dated: February 3, 2011
Received: February 4, 2011

Dear Ms. Charter:

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 Parts 801 and 809), 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 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,

Courtney 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): K100144

Device Name:
Thermo Scientific QMS® Everolimus Reagents
Thermo Scientific QMS® Everolimus Calibrators
Thermo Scientific QMS® Everolimus Controls

Indication For Use:

The QMS® Everolimus assay is intended for the quantitative determination of everolimus, the active ingredient of Zortress® in human whole blood on automated clinical chemistry analyzers. The results obtained are used as an aid in the management of kidney transplant patients receiving Everolimus therapy. This *in vitro* diagnostic device is intended for clinical laboratory use only.

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The QMS® Everolimus Control set is intended for use in quality control of the QMS® Everolimus Assay.

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)

Carol C Benson

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

510(k) K100144