K122766

510(k) Summary

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.

The assigned 510(k) number is:

Company / Contact Person

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AUG 2 0 2013

Date Prepared

September 7, 2012

Regulatory Declarations

Common / Usual Name	QMS® Everolimus Assay
Trade / Proprietary Name	Thermo Scientific QMS® Everolimus Assay
Classification Regulation	21 CFR 862.3840
Device Class	Class II
Device Regulation Panel	Clinical Chemistry and Clinical Toxicology
Product Code	OUF

Intended Use

QMS® Everolimus Reagents

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

Legally Marketed Device to Which Equivalency is Claimed

The Thermo Scientific QMS® Everolimus Assay is substantially equivalent to the previously cleared QMS® Everolimus Assay (k100144).

Device Description

The QMS® Everolimus Assay consists of separately packaged reagents (R1, R2, and Precipitation Reagent) with the following contents and configurations:

Component	Description	Configuration
R1 Antibody Reagent	<1.0% Anti-Everolimus polyclonal antibody (rabbit) in a buffer as stabilizer and <0.09% sodium azide as preservative.	1 x 22 mL
R2 Microparticle Reagent	<0.6% Everolimus-coated microparticles in buffer containing <0.05% sodium azide as preservative.	1 x 8 mL
Precipitation Reagent	Precipitating reagent, and <0.09% sodium azide as preservative.	1 x 8 mL

The reagents are supplied ready-to-use in liquid form in plastic HDPE bottles, for storage at 2 to 8°C. The reagent set is sufficient for 100 tests.

Comparison of Technological Characteristics

Comparison	Proposed Device	Predicate
Proprietary Name	Thermo Scientific QMS® Everolimus Assay	QMS® Everolimus Assay (k100144)
Intended Use	The QMS® Everolimus Assay is intended for the quantitative determination of Everolimus, in human whole blood on automated clinical chemistry analyzers. The results obtained are used as an aid in the management of kidney and liver transplant patients receiving Everolimus therapy.	The QMS® Everolimus Assay is intended for the quantitative determination of Everolimus 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 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 700 nm) 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.	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 700 nm) 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
Reagents	Three Liquid Ready-to-Use reagents (R1,R2 and Precipitation Reagent)	Three Liquid Ready-to-Use reagents (R1,R2 and Precipitation Reagent)
Reagent Storage Condition	2-8°C	2-8°C
Calibrators	Liquid Ready-To-Use (0, 1.5, 3.0, 6.0,12.0 and 20.0 ng/mL)	Liquid Ready-To-Use (0, 1.5, 3.0, 6.0,12.0 and 20.0 ng/mL)
Controls	Liquid Ready-To-Use (Low, Medium, High)	Liquid Ready-To-Use (Low, Medium, High)
Calibrators and Controls Storage Condition	-20°C ± 5°C	-20°C ± 5°C

Note: The proposed device is the same assay as the predicate device.

Performance Testing Summary

Analytical Sensitivity (LDD)

Twenty one replicates of Calibrator A were tested in the QMS® Everolimus Assay. The results demonstrate that the LDD is ≤0.51 ng/mL which is in agreement with our currently cleared labeling.

Functional Sensitivity (LOQ)

Functional Sensitivity determines the lowest concentration for which acceptable inter-assay precision and recovery is observed at a 20%CV. The results demonstrate that the LOQ is 2.0 ng/mL, which is in agreement with our currently cleared labeling.

Precision and Accuracy

Everolimus samples were tested for precision following a CLSI protocol. In the study, the total run %CV was less than or equal to 10.0% which is in agreement with our currently cleared labeling.

Method Comparison

Samples were tested in the QMS® Everolimus Assay and compared to LC/MS. The method comparison exhibited correlated well with LC/MS as follows: $y = 1.07x + 0.19$, $R = 0.97$.

Dilution Recovery

Samples were tested to demonstrate linearity throughout the assay range of 2-20 ng/mL. Results demonstrate that the assay performs in a linear fashion which is in agreement with our currently cleared labeling.

Conclusion

As summarized, the modification to the indications for use in the Thermo Scientific QMS® Everolimus Assay is substantially equivalent to the originally cleared product (k100144). Substantial equivalence has been demonstrated through performance testing (Section 18) to verify that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 20, 2013

Microgenics Corporation
C/O Karen Lee
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Re: K122766
Trade/Device Name: Thermo Scientific QMS® Everolimus Assay
Regulation Number: 21 CFR 862.3840
Regulation Name: Sirolimus test system
Regulatory Class: II
Product Code: OUF
Dated: July 25, 2013
Received: July 29, 2013

Dear Ms. Lee:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S 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 Statement

510(k) Number (if known)
k122766

Device Name
Thermo Scientific QMS® Everolimus Assay

Indications For Use

QMS® Everolimus Reagents

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 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)

Katherine Serrano -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k122766