K091617

JUL 17 2009

510K 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

Thermo Fisher Scientific Inc
Seradyn, Inc
7998 Georgetown Road, Suite 1000
Indianapolis, IN 46268

Establishment registration No: 1836010

Jack Rogers
Sr. Manager of Regulatory Affairs
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DATE PREPARED

June 2, 2009

DEVICE NAME

Trade Name:	QMS® Lidocaine Calibrators
Common Name:	Calibrators, Drug Specific
Device Classification:	21 CFR 862.3200; Clinical Toxicology Calibrator; Class II

INTENDED USE

The QMS Lidocaine Calibrator set is intended for use in calibration of the QMS Lidocaine assay.

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCY IS CLAIMED

Roche Preciset TDM II Calibrators K031856

DESCRIPTION OF DEVICE

The QMS Lidocaine Calibrator set is a six-level set (0, 0.5, 1.0, 2.5, 5.0, 10 µg/mL) of single analyte (lidocaine) calibrators.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The QMS Lidocaine Calibrators are prepared by quantitative addition of lidocaine to human serum, with an added preservative. Lidocaine is added in the same quantities as the predicate, multi-analyte calibrators, in order to achieve a 6-level set of calibrators.

	Device QMS Lidocaine Calibrators	**Predicate** Roche Preciset TDM II Calibrators
Intended Use	The QMS Lidocaine Calibrator set is intended for use in calibration of the QMS Lidocaine assay.	The Preciset TDM II Calibrators are designed for the calibration of the Roche assays for the quantitative determination of digitoxin, amikacin, lidocaine, N-acetylprocainamide, procainamide and quinidine in human serum and plasma on automated clinical chemistry analyzers.
Components	6-level set of calibrators each containing lidocaine at the following concentrations: 0, 0.5, 1.0, 2.5, 5.0, 10 µg/mL	Mixture of 6 different drugs, including lidocaine at the following concentrations: 0, 0.5, 1.0, 2.5, 5.0, 10 µg/mL
Matrix	Human serum	Human serum

CONCLUSION

As summarized above, the QMS Lidocaine Calibrators are substantially equivalent to the Roche Preciset TDM II Calibrators. 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 Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Thermo Fisher Scientific
c/o Mr. Jack Roger
Manager Regulatory Affairs
Seradyn, Inc
7998 Georgetown Road, Suite 1000
Indianapolis, IN 46268

JUL 17 2009

Re: k091617
Trade Name: QMS Lidocaine Calibrators
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrators
Regulatory Class: Class II
Product Codes: DLJ
Dated: June 02, 2009
Received: June 03, 2009

Dear Mr. Roger:

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 C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091617

Device Name: QMS® Lidocaine Calibrators

Indications for Use:

The QMS Lidocaine Calibrator set is intended for use in calibration of the QMS Lidocaine assay.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) And/Or Over-The-Counter Use _____ (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 Diagnostic Device Evaluation and Safety (OIVD)

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

510(k) _____k091617_____