NOV 1 8 2005

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: K051211

COMPANY/CONTACT PERSON

Seradyn, Inc
7998 Georgetown Road, Suite 1000
Indianapolis, IN 46268

Establishment registration No: 1836010

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Manager of Regulatory Affairs
Telephone: (317) 610-3823
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DATE PREPARED

November 18, 2005

DEVICE NAME

Trade Name:	QMS® Zonisamide
Common Name:	Homogeneous Particle-Enhanced Turbidimetric Immunoassay
Device Classification:	21 CFR 862.3350 Diphenylhydantoin Test System; Class II

INTENDED USE

The QMS® Zonisamide assay is intended for the quantitative determination of zonisamide in human serum or plasma on automated clinical chemistry analyzers.

Zonisamide concentrations can be used as an aid in management of patients treated with zonisamide.

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

The QMS® Zonisamide Control set is intended for use in quality control of the QMS Zonisamide assay.

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCY IS CLAIMED

Innofluor® Phenytoin (K955562)

DESCRIPTION OF DEVICE

The QMS® Zonisamide assay system is a homogeneous assay utilizing particle agglutination technology and is based on the competitive binding principle.

The assay consists of reagents R1: anti-Zonisamide rabbit polyclonal antibody and R2: Zonisamide-coated microparticles. A six-level set of QMS® Zonisamide Calibrators (A through F) is used to calibrate the assay. A three-level set of QMS® Zonisamide Controls (1 through 3) is used for quality control of the assay.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Device QMS® Zonisamide	**Predicate** Innofluor® Phenytoin
Intended Use	The QMS Zonisamide assay is intended for the quantitative determination of zonisamide in human serum or plasma on automated clinical chemistry analyzers.	The Innofluor Phenytoin assay is intended for the quantitative determination of total phenytoin.
Indications for Use	Zonisamide concentrations can be used as an aid in management of patients treated with zonisamide.	Therapeutic drug monitoring.
Methodology	Homogeneous particle-enhanced turbidimetric immunoassay (particle agglutination)	Fluorescence Polarization Immunoassay (FPIA) technology.
Reagent Components	Two (2) reagent system: • Anti-Zonisamide Antibody Reagent (R1) in buffers containing stabilizers with sodium azide • Zonisamide-coated Microparticle Reagent (R2) in buffer containing stabilizers with sodium azide	Three (3) reagent system: • A Phenytoin Antiserum (Sheep) in buffer with protein stabilizer and Sodium azide. • T Phenytoin Fluorescein Tracer in buffer with protein stabilizer, surfactant and Sodium azide • B Pre-Treatment Buffer with surfactant and Sodium azide
Calibration	QMS Zonisamide Calibrators – six levels	Innofluor Phenytoin Calibrators – six levels
Quality Control	QMS Zonisamide Controls – three levels	N/A

SUMMARY OF CLINICAL TESTING

Accuracy and Linearity

Accuracy and linearity were determined by a study based on the NCCLS guideline *EP6: Evaluation of the Linearity of Quantitative Measurement.*

Sensitivity

The Analytical Sensitivity or Least Detectable Dose (LDD) of the assay was determined to be 1.0 µg/mL.

The Functional Sensitivity or Limit of Quantitation (LOQ) of the assay was determined to be 3.0 µg/mL.

Assay Range

Based on the Accuracy, Linearity, and Sensitivity (LDD and LOQ) data, the package insert claim for the reportable range for the assay is 3.0 to 50.0 µg/mL.

Method Comparison

Correlation studies were conducted using NCCLS Guideline *EP9: Method Comparison and Bias Estimation Using Patient Samples* as a guideline to compare accuracy of recovery of Zonisamide in serum and plasma assayed by the QMS® Zonisamide assay to an HPLC reference method.

Precision

A precision study was performed using the National Committee for Clinical Laboratory Standards (NCCLS) guideline *EP5: Evaluation of Precision Performance of Clinical Chemistry Devices.*

Specificity

There are two known major metabolites of zonisamide: N-acetyl zonisamide (NAZ) and sulfamoyl acetyl phenol (SMAP). Testing results indicated that there is no significant cross-reactivity for either of these metabolites.

Interferences

Interference studies were conducted using NCCLS Guideline *EP7: Interference Testing in Clinical Chemistry.* The results of the study indicated that of 26 drugs tested, none showed cross-reactivity in the QMS zonisamide assay system.

CONCLUSION

As summarized above, the QMS® Zonisamide assay is substantially equivalent to the Innofluor® Phenytoin 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

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 8 2005

Mr. Jack Rogers
Manager of Regulatory Affairs
Seradyn, Inc.
7998 Georgetown Road, Suite 1000
Indianapolis, IN 46268

Re: k051211
Trade/Device Name: QMS® Zonisamide Assay
QMS® Zonisamide Calibrator Set
QMS® Zonisamide Control Set
Regulation Number: 21 CFR 862.3350
Regulation Name: Diphenylhydantoin test system
Regulatory Class: Class II
Product Code: NWM, LAS, DLJ
Dated: November 9, 2005
Received: November 10, 2005

Dear Mr. Rogers:

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

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 predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
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): K051211

Device Name: QMS® Zonisamide

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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 Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K051211