K070645

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

MAY 17 2007

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

Establishment registration No: 1836010

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DATE PREPARED

March 5, 2007

DEVICE NAME

Trade Name:	Seradyn QMS® Topiramate
Common Name:	Homogeneous Particle-Enhanced Turbidimetric Immunoassay
Device Classification:	21 CFR 862.3660; Phenobarbital Test System; Class II

INTENDED USE

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

The results obtained are used in the diagnosis and treatment of topiramate overdose and in monitoring levels of topiramate to help ensure appropriate therapy.

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCY IS CLAIMED

Seradyn Innofluor® Topiramate assay K970510

DESCRIPTION OF DEVICE

The Seradyn QMS® Topiramate assay is a homogeneous particle-enhanced turbidimetric immunoassay. The assay is based on competition between drug in the sample and drug coated onto a microparticle for antibody binding sites of the topiramate antibody reagent. The topiramate-coated microparticle reagent is rapidly agglutinated in the presence of the anti-topiramate antibody reagent and in the absence of any competing drug in the sample. The rate of absorbance change is measured photometrically. When a sample containing topiramate is added, the agglutination reaction is partially inhibited, slowing down the rate of absorbance change. A concentration-dependent classic agglutination inhibition curve can be obtained with maximum rate of agglutination at the lowest topiramate concentration and the lowest agglutination rate at the highest topiramate concentration.

The assay consists of reagents R1: anti-topiramate polyclonal antibody and R2: topiramate-coated microparticles. A six-level set of Seradyn QMS® Topiramate Calibrators is used to calibrate the assay. A three-level set of Seradyn QMS® Topiramate Controls is used for quality control of the assay.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Device Seradyn QMS® Topiramate	**Predicate** Seradyn Innofluor® Topiramate
Intended Use	The QMS Topiramate assay is intended for the quantitative determination of topiramate in human serum or plasma on automated clinical chemistry analyzers.	The Innofluor Topiramate assay is intended for the quantitative determination of total topiramate in serum or heparinized plasma by fluorescence polarization immunoassay (FPIA). The assay system is for use on the TDx® or the TDxFLx® (TDx/TDxFLx) analyzer.
Indications for Use	The measurements obtained are used in the diagnosis and treatment of topiramate overdose and in monitoring levels of topiramate to help ensure appropriate therapy.	The measurements obtained are used in monitoring levels of topiramate to ensure appropriate therapy.
Methodology	Homogeneous particle-enhanced turbidimetric immunoassay (particle agglutination) (PETIA)	Fluorescence Polarization Immunoassay (FPIA)
Reagent Components	Two (2) reagent system: Anti-topiramate Antibody Reagent (R1) in buffers containing protein stabilizers with sodium azide Topiramate-coated Microparticle Reagent (R2) in buffer containing surfactant as stabilizers with sodium azide	Three (3) reagent system: • Topiramate Antiserum (A) (Sheep) in buffer with protein stabilizer and <0.1% sodium azide • Topiramate-fluorescein Tracer (T) in buffer with surfactant, protein stabilizer, and <0.1% sodium azide • Pretreatment Buffer (B) with surfactant

SUMMARY OF CLINICAL TESTING

Accuracy

Accuracy by Recovery was determined by diluting the high calibrator to 12 concentrations across the assay range. The samples were analyzed in triplicate.

THEORETICAL CONC. (µg/mL)	**Rep 1**	**Rep 2**	**Rep 3**	**Mean Result**	**% Recovery** Acceptance Criteria: 100±10%
32.00	33.57	32.63	31.24	32.48	101.5%
24.00	24.26	24.41	24.83	24.50	102.1%
16.00	16.88	16.57	16.78	16.74	104.6%
8.00	8.27	8.30	8.48	8.35	104.4%
6.40	6.60	6.59	6.63	6.61	103.3%
3.20	3.45	3.41	3.54	3.47	108.4%
2.56	2.60	2.70	2.70	2.67	104.3%
1.92	2.16	2.03	2.15	2.11	109.9%
1.60	1.59	1.71	1.66	1.65	103.1%
1.28	1.30	1.33	1.36	1.33	103.9%
Mean Percent Recovery					104.6 %

Linearity

Linearity by Dilution was determined by a study based on the NCCLS guideline *EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach.*

Estimated Value (µg/mL)	Dilution Factor	Result	1st Order Predicted Result	2nd Order Predicted Result	Percent Difference Acceptance Criteria: ±10%
35	0.8750	36.57	36.76	36.78	-0.04%
30	0.7500	31.87	31.52	31.53	0.00%
20	0.5000	20.86	21.05	21.04	0.06%
15	0.3750	15.89	15.82	15.80	0.09%
10	0.2500	10.54	10.58	10.57	0.10%
5	0.1250	5.28	5.35	5.34	0.06%
3	0.0750	3.11	3.25	3.25	-0.02%
2	0.0500	2.22	2.20	2.21	-0.13%
1.5	0.0375	1.68	1.68	1.68	-0.25%

Sensitivity

The LOQ of the assay is defined as the lowest drug concentration for which acceptable inter-assay precision is observed (≤20% CV, with recovery ± 15%).

Based on the results, the package insert claim for LOQ will be 1.5 µg/mL.

Assay Range

Based on the Accuracy, Linearity, and Sensitivity (LOQ) data, the package insert claim for the reportable range for the assay will be 1.5 to 32.0 µg/mL.

Method Comparison

A study was conducted according to NCCLS Guideline *EP9-A2: Method Comparison and Bias Estimation Using Patient Samples* to compare accuracy of recovery of topiramate assayed by the QMS® Topiramate assay to that of the predicate Innofluor® Topiramate assay.

Mean values for the Innofluor reference method were plotted against those for the QMS method. The results using Passing - Bablok parameters are:

N = 148
Slope = 0.962
y-intercept = 0.228
R^2 = 0.986

Results show excellent correlation between the two assays.

Precision

A precision study was performed using the National Committee for Clinical Laboratory Standards (NCCLS) guideline *EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods.*

			Within Run		BETWEEN DAY		Total	
Control	N	Mean (µg/mL)	SD	CV (%)	SD	CV (%)	SD	CV (%)
1	80	2.94	0.0813	2.77	0.0617	2.10	0.1238	4.22
2	80	10.14	0.1858	1.83	0.2371	2.34	0.3418	3.37
3	80	25.69	0.8295	3.23	0.7374	2.87	1.1405	4.44

Acceptance Criteria: < 10% total CV

Specificity

Metabolites of topiramate are found primarily in urine of patients being administered topiramate therapy. They are not however seen at clinically significant levels in plasma or serum. The QMS topiramate assay serum and plasma results are unlikely to be affected by metabolism of topiramate drug.

Interferences

Interference studies were conducted using NCCLS Guideline *EP7-A2: Interference Testing in Clinical Chemistry.*

1) Endogenous Substances and HAMA

Clinically high concentrations of the following potential interferents were added to serum with known levels of topiramate (approximately 5 and 20 µg/mL). Each sample was assayed using the QMS Topiramate assay, along with a serum control of topiramate. All substances resulted in ≤10% error in detecting topiramate.

Interfering Substance	Interferent Concentration
Albumin	12 g/dL
Bilirubin	70 mg/mL
Cholesterol	250 mg/mL
Gamma-Globulin	12 g/dL
HAMA-1*	Normal Serum Levels
HAMA-2*	Normal Serum Levels
Hemoglobin	1000 mg/dL
Heparin	185.5 USP/mL
Rheumatoid Factor	500 IU/mL
Triglycerides	825 mg/dL
Uric Acid	30 mg/dL

* Human anti-mouse antibodies

2) Common Co-Administered Drugs

Studies were conducted to examine if any of the commonly administered compounds have any effect on the recovery of topiramate concentration. A high concentration of each compound was spiked into normal human serum with known levels of topiramate (approximately 5 and 20 µg/mL) and assayed along with a serum control of topiramate. All compound resulted in ≤10% error in detecting topiramate.

Compound	Compound Concentration (µg/mL)	Compound	Compound Concentration (µg/mL)
Acetaminophen	31	Lamotrigine	45
Acetazolamide	40	Levetiracetam	124
Alprazolam	2.0	Methysergide	5.2
Amitriptyline	1.0	Metoprolol	5.25
Acetylsalicylic acid	67	Nadolol	121
Atenolol	10.33	Naproxen	509
Caffeine	60	Nimodipine	75
Carbamazepine	30	Nortriptyline	1.0
Chlorthalidone	64	Phenelzine	14.38
Clonazepam	0.18	Phenobarbital	40
Clorazepate	2.0	Primidone	40
Diazepam	5.1	Protriptyline	1.03
Dichlorphenamide	32	Salicylic Acid	598
Ethosuxamide	252	Sulfanilamide	1500
Famotidine	0.97	Tolbutamide	642
Felbamate	243.33	Valproic Acid	100.67
Flurazepam	17.5	Verapamil	1.6
Furosemide	3.7	Viagabatrin	112
Gabapentin	93	Zonisamide	122
Hydrochlorothiazide	6.0		

Drugs tested that that may cross react with >10% error:

- Ibuprofen
- Phenytoin
- Tiagabine

3) Anticoagulants

Studies were conducted to determine the performance characteristics of the assay for both serum and plasma samples containing topiramate.

The results indicate that there is no significant difference between the recovery of topiramate in serum or plasma. The collection tubes evaluated show no adverse effects on the recovery of topiramate, within the experimental error for the spiking study.

A claim for assay application to both serum and plasma samples is thus supported.

On-Board Stability

1) Calibration Curve stability

Calibration curve stability of a period of 27 days is supported by the data.

2) Reagent On-Board Stability

A 60 day on-board reagent stability claim is supported by the data.

CONCLUSION

As summarized above, the Seradyn QMS® Topiramate assay is substantially equivalent to the Seradyn Innofluor® Topiramate 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
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Rockville MD 20850

Seradyn, Inc.
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Indianapolis, IN 46268-5620

MAY 17 2007

Re: k070645
Trade/Device Name: Seradyn QMS® Topiramate
Regulation Number: 21 CFR 862.3660
Regulation Name: Phenobarbital test system.
Regulatory Class: Class II
Product Code: NWM
Dated: March 05, 2007
Received: March 08, 2007

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 CFR Part 807); labeling (21 CFR Parts 801 and 809); 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 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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

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Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
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Enclosure

Indications for Use

510(k) Number (if known): K070645

Device Name: Seradyn QMS® Topiramate

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The results obtained are used in the diagnosis and treatment of topiramate overdose and in monitoring levels of topiramate to help ensure appropriate therapy.

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

K070645