DEC 2 3 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: K052826

COMPANY/CONTACT PERSON

Seradyn, Inc
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DATE PREPARED

October 4, 2005

DEVICE NAME

Trade Name:	QMS® Quinidine
Common Name:	Homogeneous Particle-Enhanced Turbidimetric Immunoassay
Device Classification:	21 CFR 862.3320; Enzyme Immunoassay, Quinidine; Class II

INTENDED USE

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

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

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCY IS CLAIMED

Abbott TDx/TDxFLx Quinidine

DESCRIPTION OF DEVICE

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

In particle agglutination assays, the degree of agglutination 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® Quinidine 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 assay consists of reagents R1: anti-quinidine monoclonal antibody and R2: quinidine-coated microparticles. A six-level set of QMS® Quinidine Calibrators (A through F) is used to calibrate the assay.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

	Device Seradyn QMS® Quinidine	**Predicate** Abbott TDx/TDxFLx Quinidine
Intended Use	The QMS® Quinidine assay is intended for the quantitative determination of quinidine in human serum or plasma on automated clinical chemistry analyzers.	The TDx/TDxFlx Quinidine assay is a reagent system for the quantitative measurement of quinidine in serum or plasma.
Indications for Use	The measurements obtained are used in the diagnosis and treatment of quinidine overdose and in monitoring levels of quinidine to ensure appropriate therapy.	The measurements obtained are used in monitoring levels of quinidine to ensure appropriate therapy.
Methodology	Homogeneous particle-enhanced turbidimetric immunoassay (particle agglutination)	Fluorescence Polarization Immunoassay (FPIA) technology.
Reagent Components	Two (2) reagent system: • Anti-Quinidine Antibody Reagent (R1) in buffers containing protein stabilizers with sodium azide • Quinidine-coated Microparticle Reagent (R2) in buffer containing surfactant as stabilizers with sodium azide	Three (3) reagent system: • Pretreatment Solution (P) Surfactant in buffer containing N-N-dimethylformamide and protein stabilizer and sodium azide. • S Quinidine Antiserum (Goat) in buffer with protein stabilizer and Sodium azide. • T Quinidine Fluorescein Tracer in buffer with protein stabilizer surfactant N-N-dimethylformamide and Sodium azide
Calibration	QMS Quinidine Calibrators - six levels	X Systems Quinidine Calibrators - six levels

SUMMARY OF CLINICAL TESTING

Accuracy

Accuracy by Recovery was determined by spiking USP traceable quinidine into human serum negative for the drug to achieve concentrations across the assay range. The samples were analyzed in duplicate with the QMS Quinidine assay.

THEORETICAL CONC. (µg/mL)	Rep 1	Rep 2	Mean Recovered Conc.	SD	CV	% Recovery Acceptance Criteria: 100±10%
2.0	2.06	1.81	1.94	0.12	6.50	97.00
4.0	3.94	3.95	3.95	0.01	0.13	98.75
8.0	7.81	7.76	7.79	0.02	0.32	97.38
					Mean Percent Recovery	97.71

Linearity

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

A linear regression analysis plot of USP Quinidine against recovered quinidine resulted in a line with a correlation coefficient (R^2) of 0.9995, demonstrating that the assay is linear.

THEORETICAL CONC. (µg/mL)	Rep 1	Rep 2	Mean Recovered Conc.	SD	CV	% Recovery
0.25	0.25	0.18	0.22	0.04	15.90	88.00
0.75	0.71	0.73	0.72	0.01	1.39	96.00
1.5	1.42	1.41	1.42	0.01	0.35	94.67
3.0	2.98	2.98	2.98	0.00	0.00	99.33
6.0	6.22	6.18	6.2	0.02	0.32	103.33
					Mean Percent Recovery	96.27

Sensitivity

The Analytical Sensitivity or Least Detectable Dose (LDD) of the assay is defined as the concentration at which the lowest concentration is distinguishable from zero with 95% confidence.

The average LDD is 0.09 µg/mL, supporting a claim of 0.2 µg/mL

Assay Range

Based on the Accuracy, Linearity, and Sensitivity (LDD) data, the package insert claim for the reportable range for the assay will be 0.2 to 8.0 µg/mL.

Method Comparison

A study was conducted according to NCCLS Guideline *EP9: Method Comparison and Bias Estimation Using Patient Samples* to compare accuracy of recovery of quinidine in serum assayed by the QMS® Quinidine assay to the Abbott TDx/TDxFLx® Quinidine assay.

Mean values for the TDx reference method were plotted against those for the QMS on Hitachi 717. The results using Passing - Bablok parameters are:

N = 50
Slope = 1.062
y-intercept = -0.213
R^2 = 0.978

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: Evaluation of Precision Performance of Clinical Chemistry Devices.*

			Within Run		BETWEEN DAY		Total	
Control	N	Mean (µg/mL)	SD	CV (%)	SD	CV (%)	SD	CV (%)
1	80	1.02	0.06	5.83	0.01	1.53	0.09	9.09
2	80	3.17	0.08	2.45	0.00	0.00	0.20	6.37
3	80	5.18	0.08	1.62	0.00	0.00	0.30	5.83

Acceptance Criteria: < 10% total CV

Specificity

Metabolites of quinidine include: 3-Hydroxyquinidine; Quinidine-N-oxide; O-Desmethylquinidine; 2-Oxoquinidinone; and 10,11-Dihydroquinidinediol. The most important metabolite is 3-Hydroxyquinidine, serum levels of which can approach those of quinidine in patients receiving conventional doses of the drug. It is also reported to have an antiarrhythmic potency similar to that of quinidine.

	N	Control Mean	Conc. Of Cross-reactant spiked µg/mL	Mean	SD	CV	Da-Dt	% Cross-Reactivity
3-Hydroxyquinidine	3	5.71	5	5.78	0.12	2.01	0.06	1.27
Quinidine-N-oxide	3	5.72	5	8.99	0.27	2.96	3.28	65.60
O-Desmethylquinidine	3	5.72	5	6.55	0.02	0.35	0.84	16.80
2-Oxoquinidinone	3	5.71	5	6.09	0.03	0.47	0.38	7.60
10,11-Dihydroquinidinediol	3	5.37	5	5.99	0.17	2.81	0.63	12.53

Interferences

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

1) Endogenous Substances

Interfering Substance	Interferent Concentration	N	Target (No Interferent) µg/mL	Mean Recovery µg/mL	% Recovery Acceptance Criteria: 100±10%
Bilirubin	15 mg/dL	2	5.82	5.98	103.0
Hemoglobin	10 g/L	2	5.82	5.84	100.0
Triglyceride	1127 mg/dL	3	6.05	5.58	92.18
Total Protein	12 g/dL	3	6.32	6.30	99.68

2) HAMA

	Rep 1 µg/mL	Rep 2 µg/mL	Mean Recovery µg/mL	SD	CV	% Recovery Acceptance Criteria: 100±10%
Control	6.59	6.24	6.42	0.18	2.73	------
HAMA Type-1	5.79	5.91	5.85	0.08	1.37	91.12
HAMA Type-2	5.80	5.84	5.82	0.02	0.34	90.65

3) Common Co-Administered Drugs

Cross-reactant Drug	Conc. Tested µg/mL	Percent Cross-Reactivity/Conc (µg/mL)
Acetominophen	200	ND
Acetyl cysteine	1000	ND
Acetylsalycilic acid	3000	ND
Ampicillin	50	ND
Ascorbic acid	30	-0.51
Cefoxitin	1000	ND
Cyclosporine	600	ND
Digitoxin	0.25	ND
Digoxin	0.02	0.02
Disopyramide	50	0.76
Ephedrin	1000	ND
Furosemide	100	ND
Hydrochlorothiazide	40	ND
Ibuprofen	7000	ND
Isoproterenol	0.06	ND
Levodpa	1000	ND
Lidocaine	50	ND
Metronidazole	1000	ND
N-Acetylprocainamide	400	ND
Phenylbutazone	1000	ND
Phenytoin (DPH)	200	ND
Procainamide	100	ND
Propranolol	1	4.33
Quinine	5	14.80
Reserpine	1000	ND
Rifampicin	50	ND
Tetracycline	2000	ND
Theophylline	200	ND

*ND = not detected

4) Anticoagulants

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

The results indicate that there is no significant difference between the recovery of quinidine in serum or plasma. The collection tubes evaluated show no adverse effects on the recovery of quinidine, 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) <u>Calibration Curve stability</u>

Calibration curve stability of a period of 28 days is supported by the data.

2) <u>Reagent On-Board Stability</u>

A 25 day on-board reagent stability claim is supported by the data.

CONCLUSION

As summarized above, the QMS® Quinidine assay is substantially equivalent to the Abbott TDx®/TDxFLx® Quinidine 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

DEC 2 3 2005

Mr. Jack Roger
Manager of Regulatory Affairs
Seradyn, Inc.
7998 Georgetown Road
Suite 100
Indianapolis, IN 46268

Re: k052826
Trade/Device Name: QMS® Quinidine
Regulation Number: 21 CFR 862.3320
Regulation Name: Digoxin test system
Regulatory Class: Class II
Product Code: LBZ
Dated: October 4, 2005
Received: October 5, 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 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) 276-0484. 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): K052826

Device Name: QMS® Quinidine

Indications for Use:

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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)

Ann Chappie
Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K052826