K060998

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: K060998

COMPANY/CONTACT PERSON

JUL 2 1 2006

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Establishment registration No: 1836010

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DATE PREPARED

June 22, 2006

DEVICE NAME

Trade Name:	QMS® Tobramycin
Common Name:	Homogeneous Particle Enhanced Turbidimetric Immunoassay
Device Classification:	21 CFR 862.3900; Tobramycin Test System; Class II

INTENDED USE

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

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

LEGALLY MARKETED DEVICE TO WHICH EQUIVALENCY IS CLAIMED

Abbott TDx/TDxFLx Tobramycin assay (k802668)

DESCRIPTION OF DEVICE

The QMS® Tobramycin 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- tobramycin monoclonal antibody and R2: tobramycin -coated microparticles. A six-level set of QMS® Tobramycin Calibrators (A through F) is used to calibrate the assay.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

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

SUMMARY OF CLINICAL TESTING

Accuracy

Accuracy by Recovery was determined by spiking tobramycin into human serum negative for the drug to achieve concentrations across the range of the assay. The samples were analyzed in triplicate with the QMS Tobramycin assay.

Theoretical Conc. (µg/mL)	**Rep 1 (µg/mL)**	**Rep 2 (µg/mL)**	**Rep 3 (µg/mL)**	**Mean Recovered Conc. (µg/mL)**	**SD**	**CV(%)**	**% Recovery** Acceptance Criteria: 100±10%
1.5	1.39	1.32	1.37	1.36	0.036	2.65	90.67%
3.0	2.82	2.82	2.71	2.78	0.064	2.30	92.67%
4.5	4.24	4.39	4.26	4.30	0.081	1.88	95.56%
6.0	5.77	5.87	5.95	5.86	0.090	1.54	97.67%
					Mean Percent Recovery		94.14%

Linearity

A tobramycin in human serum pool was diluted with human serum negative for tobramycin to achieve concentrations across the range of the assay. The samples were analyzed in triplicate with the QMS Tobramycin assay.

A linear regression analysis plot of the data resulted in a line with a correlation coefficient (R^2) of 0.9996, demonstrating that the assay is linear.

Theoretical Conc. (µg/mL)	**Rep 1 (µg/mL)**	**Rep 2 (µg/mL)**	**Rep 3 (µg/mL)**	**Mean Recovered Conc. (µg/mL)**	**SD**	**CV(%)**	**% Recovery** Acceptance Criteria: 100±10%
0.465	0.42	0.51	0.52	0.48	0.055	11.395	104.05%
0.929	0.94	0.95	0.83	0.91	0.067	7.3437	97.60%
1.858	1.85	1.79	1.82	1.82	0.030	1.6484	97.95%
3.716	3.54	3.51	3.55	3.53	0.021	0.5892	95.08%
5.574	5.51	5.42	5.49	5.47	0.047	0.8634	98.19%
7.432	7.39	7.36	7.24	7.33	0.079	1.0828	98.63%
9.290	9.22	9.30	9.35	9.29	0.066	0.7059	100.00%
11.148	10.96	11.05	11.10	11.04	0.071	0.6428	99.00%
13.006	13.03	12.89	13.07	13.00	0.095	0.7272	99.93%
14.864	15.11	14.55	14.96	14.87	0.290	1.949	100.06%
16.722	15.30	16.81	16.65	16.25	0.829	5.1034	97.20%
18.580	18.65	18.54	17.33	18.17	0.732	4.0302	97.81%
					Mean Percent Recovery		98.79%

Sensitivity

The Functional Sensitivity or Limit of Quantitation (LOQ) of the assay is defined as the lowest concentration of an analyte that can be reliably detected and at which the total error meets accuracy requirements. The LOQ was determined to be 0.4 µg/mL.

Assay Range

Based on the Accuracy, Linearity, and Sensitivity data, the package insert claim for the reportable range for the assay will be 0.4 to 10 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 tobramycin in serum assayed by the QMS® Tobramycin assay to the Abbott TDx/TDxFLx® Tobramycin assay.

Mean values for the TDx reference method were plotted against those for the QMS on Hitachi 917 . The results, using Passing – Bablok parameters, are:

N = 67
Slope = 0.979
y-intercept = -0.086
R = 0.992
R^2 = 0.984

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 Clinical Chemistry Devices.*

			Within Run		Between Day		Total	
	N	Mean µg/mL	SD	CV (%)	SD	CV (%)	SD	CV (%)
Low Control	80	1.11	0.022	1.98	0.054	4.86	0.084	7.57
Mid Control	80	3.83	0.050	1.31	0.120	3.13	0.162	4.23
High Control	80	8.06	0.131	1.63	0.057	0.71	0.343	4.26

Acceptance Criteria: < 10% total CV

Specificity

The QMS Tobramycin assay utilizes a mouse derived (ascites) tobramycin monoclonal antibody directed against tobramycin. There are no metabolites of tobramycin.

Interferences

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

A. Endogenous Substances

Interfering Substance	Interferent Concentration	N	Target (No Interferent) µg/mL	Mean Recovery µg/mL	% Recovery Acceptance Criteria: 100±10%
Albumin	12 g/dL	3	8.53	8.33	97.66%
Bilirubin	400 mg/dL	3	8.41	7.76	92.27%
Cholesterol	500 mg/dL	3	7.02	7.43	105.84%
Gamma Globulins (IgG)	12 g/dL	3	7.02	6.84	97.44%
Hemoglobin	20 mg/dL	3	8.09	7.86	97.16%
Hemoglobin	500 mg/dL	3	8.09	8.79	108.65%
Uric Acid	20 mg/dL	3	7.02	6.34	90.31%
Rheumatoid Factor	705 IU/mL	3	6.99	7.22	103.29%
Triglyceride	1200 mg/dL	3	6.89	7.58	90.98%

B. HAMA

	Rep 1 µg/mL	Rep 2 µg/mL	Rep 3 µg/mL	Mean Recovery µg/mL	SD	%CV	% Recovery Acceptance Criteria: 100±10%
HAMA Type-1	7.53	7.42	7.53	7.49	0.08	1.08%	92.58%
Control	8.11	8.14	8.03	8.09	0.08	0.99%	100.00%
HAMA Type-2	7.49	7.69	7.60	7.59	0.06	0.79%	93.82%
Control	8.11	8.14	8.03	8.09	0.08	0.99%	100.00%

C. Common Co-Administered Drugs

Cross-reactant Drug	Conc. Tested µg/mL	Percent Cross-Reactivity
5-Fluorocytosine	30	0.29
Acetaminophen	200	ND
Amikacin	200	12.41
Amphotericin B	100	ND
Ampicillin	50	ND
Carbenicillin	2500	-0.13
Cefamandole Nafate	250	ND
Cephalexin	320	ND
Cephalosporin C	1000	ND
Cephalothin	1000	ND
Chloramphenicol	250	ND
Clindamycin	2000	ND
Ephedrine	1000	ND
Erythromycin	500	ND
Ethacrynic Acid	400	ND
Furosemide	100	ND
Fusidic Acid	1000	ND
Gentamicin	100	ND
Ibuprofen	7000	ND
Kanamycin A	400	6.86
Kanamycin B	400	6.61
Lincomycin	2000	ND
Methicillin	200	-0.25
Methotrexate	500	ND
Methylprednisolone	200	ND
Neomycin	1000	ND
Netilmycin	125	ND
Oxytetracycline	2000	ND
Penicillin V	100	-0.20
Prednisolone	12	0.33
Rifampicin	500	ND
Sisomycin	100	ND
Spectinomycin	100	ND
Streptomycin	400	ND
Sulfadiazine	1000	ND
Sulfamethoxazole	400	ND
Tetracycline	2000	ND
Trimethoprim	200	-0.70
Vancomycin	400	ND

*ND = Not Detected

D. Anticoagulants

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

The results indicate that there is no significant difference between the recovery of tobramycin in serum or plasma. The collection tubes evaluated show no adverse effects on the recovery of tobramycin, 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 14 days is supported by the data.

2) Reagent On-Board Stability

A 45 day on-board reagent stability claim is supported by the data.

CONCLUSION

The QMS® Tobramycin assay has been shown to be substantially equivalent to the Abbott TDx®/TDxFLx® Tobramycin assay. The performance testing verifies 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

JUL 21 2006

Earl E. Knight III, MPA
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Seradyn, Inc.
7998 Georgetown Road, Suite 1000
Indianapolis, IN 46268-5620

Re: k060998
Trade/Device Name: QMS® Tobramycin
Regulation Number: 21 CFR§ 862.3900
Regulation Name: Tobramycin test system
Regulatory Class: Class II
Product Code: LCR
Dated: June 29, 2006
Received: June 30, 2006

Dear Mr. Knight:

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): K060998

Device Name: QMS® Tobramycin

Indications for Use:

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The results obtained are used in the diagnosis and treatment of tobramycin overdose and in monitoring levels of tobramycin 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

K060998