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K 052794

5.0 510(k) SUMMARY

SUBMITTED BY:

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NAME OF DEVICE:

Trade Name:	DiaSorin ETI-MAX 3000™
Common Names/Descriptions:	Automated Laboratory Analyzer
Classification Names:	Discrete photometric chemistry analyzer for clinical use
Product Code:	JJF

PREDICATE DEVICES: Labotech (K922081) also known as the ETI-LAB Mago™ Automated EIA Processor (K973177)

INTENDED USE: The DiaSorin ETI-MAX 3000™ is a fully automated microtiter plate analyzer designed to perform the complete sample processing of qualitative and semi-quantitative assays with respect to (sample dilutions, sample and reagent dispensing, incubations, wash processes, plate transports) as well as the photometric measurement and evaluation.
The qualitative and semi-quantitative performance of the ETI-MAX 3000 ™ instrument were assessed using the DiaSorin ANAScreen ELISA kit, the DiaSorin Anti-SS-A (Ro) ELISA kit and the EuroDiagnostica AB ENA Single Well Screen Kit.

DEVICE DESCRIPTION: The ETI- MAX 3000™ is a fully automated, microtiter plate laboratory analyzer performing the complete sample processing (barcode scanner, predilution station, pipetting station, plate transport, wash station, incubators and photometric measurement). The instrument is controlled by the Windows PC software ETI- MAX 3000™. This software allows the user to process the pre-defined assays of DiaSorin.

PERFORMANCE DATA:

Performance testing of the ETI- MAX 3000™ consisted of running three FDA previously cleared Immunology assays by manual method as well as on the ETI-MAX 3000™ to evaluate analytical sensitivity, linearity, reproducibility/precision, carry-over, and method comparison/ correlation.

Analytical sensitivity - Analytical sensitivity was determined for the manual assays and assays on the ETI-MAX 3000™ by following NCCLS guideline EP-17A, Protocols for Determination of Limits of Detection and Limits of Quantitation.

Linearity - Linearity was established by testing serial dilutions of four positive sera across the full assay range for each product. The results indicated the ETI-MAX 3000™ interpretations

(positive, equivocal or negative) were within +/- 1 dilution from the interpretations for the same dilutions using the manual method.

Reproducibility/Precision for semi-quantitive and/or qualitative samples - The instrument reproducibility/precision study was conducted at two external US laboratories and at DiaSorin Inc in Stillwater MN. A coded panel comprised of 8 frozen repository serum samples was prepared at DiaSorin and provided to each site for testing by the DiaSorin ETI-MAX 3000™ instrument and the three autoimmune assays. The panel contained 6 samples near the cut-off. Each site ran the coded samples using 4 replicates per run in 1 run per day over 5 days of operation (NCCLS: EP5-A2). Three different instruments were used. The results are summarized in the tables below as sample overall mean S/CO, %CVs computed for within run, between run, total, and instrument to instrument.

Table of Precision for ANA Screen:

			mean	within run	between run	total	instrument to instrument
ID#	Site	N	(S/CO)	%CV	%CV	%CV	%CV
#1	1	20	0.98	6.6	0	6.3	
	2	20	0.86	8.5	25.7	27.1	6.8
	3	20	0.93	20.6	0	20.4	
#2	1	20	1.05	3.1	2.6	4.0	
	2	20	1.12	1.9	1.1	2.2	3.2
	3	20	1.09	2.0	0.5	2.0	
#3	1	20	0.73	4.0	2.6	4.8	
	2	20	0.51	4.2	50.4	50.6	18.6
	3	20	0.71	4.3	3.2	5.4	
#4	1	20	1.21	2.3	3.3	4.1	
	2	20	1.29	1.5	3.3	3.6	3.1
	3	20	1.25	4.3	0	4.2	
#5	1	20	1.17	4.0	2.6	4.8	
	2	20	1.22	2.4	4.0	4.6	2.7
	3	20	1.23	2.7	2.0	3.4	
#6	1	20	1.26	3.0	3.0	4.3	
	2	20	1.08	10.9	36.4	37.9	8.4
	3	19	1.23	22.0	0	21.8	
#7	1	20	1.33	2.0	3.6	4.2	
	2	20	1.34	2.7	7.0	7.5	2.8
	3	20	1.40	3.0	0	2.9	
#8	1	20	1.29	3.0	0.3	3.0	
	2	20	1.28	2.2	16.0	16.1	3.2
	3	20	1.36	2.9	4.2	5.1	

Table of Precision for ENA 6 Screen:

			mean	within run	between run	total	instrument to instrument
ID#	Site	N	(S/CO)	%CV	%CV	%CV	%CV
#1	1	20	0.52	7.1	5.1	8.7	
	2	20	0.48	3.0	8.9	9.4	4.5
	3	20	0.50	6.0	5.7	8.3	
#2	1	20	1.61	4.5	4.3	6.2	
	2	20	1.82	3.5	2.4	4.2	6.2
	3	20	1.70	2.8	4.4	5.2	
#3	1	20	1.60	3.4	6.4	7.3	
	2	20	1.63	6.8	5.9	8.9	1.6
	3	20	1.66	4.0	3.0	5.0	
#4	1	20	1.81	5.3	7.5	9.1	
	2	20	1.76	5.3	19.6	20.3	3.0
	3	20	1.87	2.8	4.2	5.0	
#5	1	20	1.25	5.0	4.9	7.0	
	2	20	1.20	10.9	20.8	23.4	3.1
	3	20	1.27	5.4	3.2	6.3	
#6	1	20	1.45	4.2	3.7	5.6	
	2	20	1.51	6.0	8.8	10.7	2.0
	3	20	1.50	4.4	4.6	6.3	
#7	1	20	1.30	3.2	2.9	4.3	
	2	20	1.50	13.7	10.2	17.1	8.3
	3	20	1.30	9.9	5.1	11.1	
#8	1	20	1.47	5.8	3.9	7.0	
	2	20	1.59	7.9	10.2	12.9	5.0
	3	20	1.45	3.4	6.5	7.4	

Table of Precision for Anti-SS-A (Ro):

			mean	within run	between run	total	instrument to instrument
ID#	Site	N	(S/CO)	%CV	%CV	%CV	%CV
#1	1	20	0.81	4.2	6.1	7.4	
	2	20	0.80	8.1	5.9	10.0	3.7
	3	20	0.86	7.1	0	7.1	
#2	1	20	0.93	3.1	4.8	5.7	
	2	20	0.88	4.7	2.8	5.5	2.9
	3	20	0.91	2.6	3.1	4.1	
#3	1	20	1.00	3.1	5.0	5.9	
	2	20	0.84	8.4	42.6	43.4	12.1
	3	20	1.07	5.1	0	4.9	
#4	1	20	1.00	4.3	3.0	5.2	
	2	20	0.80	4.8	42.0	42.3	12.2
	3	20	1.00	3.6	4.7	5.9	
#5	1	20	0.99	4.3	3.7	5.6	
	2	20	1.04	4.3	2.7	5.1	4.7
	3	20	1.08	7.0	7.7	10.4	
#6	1	20	1.01	3.4	3.9	5.2	
	2	20	0.99	3.7	3.8	5.3	2.5
	3	20	1.04	3.8	2.6	4.6	
#7	1	20	1.10	4.2	3.7	5.5	

			mean	within run	between run	total	instrument to instrument
ID#	Site	N	(S/CO)	%CV	%CV	%CV	%CV
	2	20	1.05	12.7	6.5	14.3	8.3
	3	20	1.23	6.6	3.9	7.6	
#8	1	20	1.00	3.9	3.4	5.2	
	2	20	1.03	4.3	1.4	4.5	4.7
	3	20	1.09	4.6	7.4	8.7	

Carry-over studies - Testing was conducted for all three assays and results indicated there was no carry over from the pipettor or washer.

Method Comparison/(Correlation) - The automated instrument results were compared to manual method results for all three assays using 159 retrospective samples (w/clinical history). The results are summarized below as positive, negative, and overall percent agreement with the Manual assay results with 95% exact confidence intervals.

ANA Screen	Manual Method			
ETI-Max	Positive	Negative	Equivocal	Total
Positive ≥1.0 S/CO	62	0	0	62
Negative <0.7 S/CO	0	88	3	91
Equivocal ≥0.7 and <1.0 S/CO	2	0	4	6
Total	64	88	7	159

	Percent Agreement	Exact 95% confidence interval
Positive	96.9% (62/64)	89.2 – 99.6%
Negative	100.0% (88/88)	95.9 – 100.0%
Overall	96.9% (154/159)	92.8 – 99.0%

ENA Screen	Manual Method			
ETI-Max	Positive	Negative	Equivocal	Total
Positive >1.0 S/CO	59	0	0	59
Negative <0.95 S/CO	4	92	4	100
Equivocal ≥0.95 and ≤1.0 S/CO	0	0	0	0
Total	63	92	4	159

	Percent Agreement	Exact 95% confidence interval
Positive	93.7% (59/63)	87.6 – 99.7%
Negative	100.0% (92/92)	96.1 – 100.0%
Overall	95.0% (151/159)	90.3 – 97.8%

Anti-SS-A (Ro) Qualitative	Manual Method			
ETI-Max	Positive	Negative	Equivocal	Total
Positive >1.0 S/CO	55	0	0	55
Negative <0.95 S/CO	0	104	0	104
Equivocal ≥0.95 and ≤1.0 S/CO	0	0	0	0
Total	55	104	0	159

	Percent Agreement	Exact 95% confidence interval
Positive	100.0% (55/55)	93.5 – 100.0%
Negative	100.0% (104/104)	96.5 – 100.0%
Overall	100.0% (159/159)	97.7 – 100.0%

Anti-SS-A (Ro) Semi-Quantitative	Manual Method		
ETI-Max	Positive	Negative	Total
Positive >2.0 U/mL	54	1	55
Negative ≤2.0 U/mL	0	104	104
Total	54	105	159

	Percent Agreement	Exact 95% confidence interval
Positive	100.0% (54/54)	93.4 – 100.0%
Negative	99.0% (104/105)	94.8 – 100.0%
Overall	99.4% (158/159)	96.6 – 100.0%

CONCLUSION:

The ETI-MAX 3000™ Automated Laboratory Analyzer showed equivalent performance to the correspondent manual assay methods for the FDA previously cleared assays. The results demonstrated that ETI-MAX 3000™ Automated Laboratory Analyzer can be used to automate the manual assays effectively.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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MAR 3 1 2006

DiaSorin, Inc.
c/o Ms. Carol A. DePouw
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Re: k052794
Trade/Device Name: ETI-MAX 3000™
Regulation Number: 21 CFR 862.2170
Regulation Name: Micro Chemistry Analyzer for Clinical Use
Regulatory Class: Class I
Product Code: JJF
Dated: September 29, 2005
Received: October 7, 2005

Dear Ms. DePouw:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance 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,

Robert L. Becker, Jr., M.D., Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052794

Device Name: ETI-MAX 3000™

Indications For Use:

The ETI-MAX 3000™ is a fully automated EIA microtiter plate analyzer designed to perform the complete sample processing of qualitative and semi-quantitative assays with respect to (sample dilutions, sample and reagent dispensing, incubations, wash processes, plate transports) as well as the photometric measurement and evaluation. The qualitative and semi-quantitative performance of the ETI-MAX 3000™ instrument were assessed using the DiaSorin ANAScreen ELISA kit, the DiaSorin Anti-SS-A(Ro) ELISA kit and the EuroDiagnostica AB ENA Single Well Screen kit.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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)

Maria Chan

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K052794