K993291

FEB 1 0 2000

January 8, 2000

510(k) Summary

SUBMITTED BY:

Judith J. Smith
DiaSorin, Inc.
9175 Guilford Rd. Suite 100
Columbia, MD 21046

NAME OF DEVICES:

Trade Name: Copalis® Rubella IgM Assay

Common Names/Descriptions: Immunoassay for the Detection of IgM Antibodies to Rubella virus

Classification Names: Rubella Serology Test

PREDICATE DEVICES: Abbott Laboratories IMx Rubella IgM (MEIA)

DEVICE DESCRIPTION:

INTENDED USE:

The Copalis® Rubella IgM assay uses Coupled Particle Light Scattering (Copalis®) technology in a microparticle aggregation-based immunoassay for the qualitative detection of IgM antibodies to Rubella virus in human serum and EDTA, heparin or sodium citrate plasma using the Copalis® I Immunoassay System. The test is indicated for the presumptive diagnosis of primary rubella infection.

KIT DESCRIPTION: Coupled Particle Light Scattering (Copalis®) technology

Coupled Particle Light Scattering (Copalis®) technology provides a rapid method for the measurement of antibodies to specific viral or protozoan pathogens.

The Copalis® Rubella IgM Assay is based on the principle of antibody-dependent particle aggregation as detected by measurement of changes in light scattering. The serum or plasma sample is manually pre-diluted in Sample Diluent to remove IgG and IgA antibodies. Polystyrene microparticles present in the Copalis® Test Cup are coated with Rubella viral antigen (HPV 77 strain). These microparticles aggregate in the presence of the pre-diluted human serum/plasma containing IgM antibodies to Rubella virus. After 10 minutes of agitation, the levels of aggregation are determined by measurement of the number of reacted and unreacted particles as they flow past a detector. Reactivity is assessed by the level of aggregation relative to a cutoff value. The Copalis® Rubella IgM Assay detects the presence of Rubella IgM-specific antibodies. Two levels of controls are used to monitor system performance.

PERFORMANCE DATA:

Clinical Correlation: Clinical trials were conducted at 3 sites (1 hospital clinical laboratory, 1 state laboratory and at DiaSorin) to evaluate the performance of the Copalis® Rubella IgM Assay in detecting IgM antibodies to Rubella antigen on the Copalis® I Immunoassay System. The assay performance was compared to the Abbott IMx Rubella IgM test.

Summary of Acute Adult Population for Copalis® Rubella IgM Assay

	Copalis Rubella IgM			
IMx Rubella IgM	Pos	Neg	EQ	Grand Total
Pos	70	1	0	71
Neg	1	38	0	39
EQ	1	3	0	4
Grand Total	72	42	0	114

Agreement **98.2%** (108/110)
[95% CI] [93.6 – 99.8%]

Summary of Obstetric Adult Population for Copalis® Rubella IgM Assay

	Copalis Rubella IgM			
IMx Rubella IgM	Pos	Neg	EQ	Grand Total
Pos	0	0	0	0
Neg	0	50	0	50
EQ	0	0	0	0
Grand Total	0	50	0	50

Agreement **100.0%** (50/50)
[95% CI] [92.9 – 100.0%]

Summary of Seronegative Population for Copalis® Rubella IgM Assay

	Copalis Rubella IgM			
IMx Rubella IgM	Pos	Neg	EQ	Grand Total
Pos	0	0	0	0
Neg	0	97	1	98
EQ	0	1	0	1
Grand Total	0	98	1	99

Agreement **100.0%** (97/97)
[95% CI] [96.3 – 100.0%]

Summary of Pediatric Population for Copalis® Rubella IgM Assay

	Copalis Rubella IgM			
IMx Rubella IgM	Pos	Neg	EQ	Grand Total
Pos	3	0	0	3
Neg	0	17	0	17
EQ	0	0	0	0
Grand Total	3	17	0	20

Agreement **100.0%** (20/20)
[95% CI] [83.2 – 100.0%]

Reproducibility: Reproducibility studies were performed at three sites using one lot of Copalis® Rubella IgM reagents. Assay reproducibility was determined by assaying a reproducibility panel consisting of six serum samples that covered the range of the Copalis® Rubella IgM assay. Panel members were tested in duplicate once a day for five days. Results expressed in Copalis Test Results (CTR) are summarized by combined site results.

Copalis CTR Results Sites Combined - Copalis Rubella IgM Assay

Copalis CTR			
Sample ID	**Mean**	**%CV**	**Within Run %CV**
Neg Control	100	1.7%	na
Pos Control	136	8.0%	na
NRM01-01	102	3.0%	2.2%
NRM01-02	102	2.7%	1.4%
PRM01-01	156	12.4%	8.9%
PRM01-02	142	9.8%	6.9%
PRM01-03	117	5.1%	3.8%
PRM01-04	364	18.5%	12.3%
Sample N	30	30	30

Plasma reproducibility studies were performed at DiaSorin using one lot of Copalis® Rubella IgM. Six sets of serum/ multiple plasma paired samples were prepared using EDTA, heparin and sodium citrate plasma and spanned the range of the assay. The samples were tested in duplicate once a day for 3 days.

CTR	**serum**			**EDTA plasma**			**HEPARIN plasma**			**CITRATE plasma**		
	total		within run	total		within run	total		within run	total		within run
	mean	%CV	%CV	mean	%CV	%CV	mean	%CV	%CV	mean	%CV	%CV
N1	102	2.57	1.37	102	2.43	1.37	106	1.48	0.67	102	1.20	0.35
N2	100	2.36	1.41	105	2.25	1.02	100	2.16	1.07	92	31.54	1.39
HP	200	6.23	3.54	196	8.01	4.41	176	5.71	2.39	191	10.07	2.53
LP1	130	4.32	1.66	131	5.13	1.39	125	2.90	1.17	124	3.49	0.57
LP2	139	4.90	1.31	144	5.73	3.28	145	4.10	1.94	143	3.92	1.22

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 1 0 2000

Ms. Judith J. Smith
Process Owner, Worldwide Regulatory Affairs
and Quality System
DiaSorin, Inc.
9175 Guilford Road, Suite 100
Columbia, Maryland 21046

Re: K993291
Trade Name: Copalis® Rubella IgM Assay
Regulatory Class: III
Product Code: LFX
Dated: December 13, 1999
Received: December 14, 1999

Dear Ms. Smith:

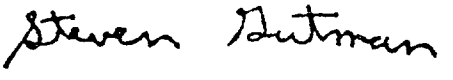
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K993291

Device Name: Copalis® Rubella IgM Assay

Indications For Use: The Copalis® Rubella IgM assay uses Coupled Particle Light Scattering (Copalis®) technology in a microparticle aggregation-based immunoassay for the qualitative detection of IgM antibodies to rubella virus in human serum and EDTA, heparin or sodium citrate plasma using the Copalis® I Immunoassay System. The test is indicated for the presumptive diagnosis of primary rubella infection.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993291

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)