

APPENDIX 5, revised.

510(k) SUMMARY

Applicant: Quest International, Inc.
1938 N.E. 148th Terrace
North Miami, FL 33181

Date prepared: May 15, 1998

Contact person: Robert A. Cort, President

Telephone: (305) 948-8788

Telefax: (305) 948-4876

Device: SeraQuest Rubella IgM

Device Classification: Class III (premarket approval)

Device Name: Rubella serological reagents (21CFR § 866.3510)

Description:

The SeraQuest Rubella IgM test is a solid-phase enzyme immunoassay (EIA), which is performed in microwells, at room temperature, in three thirty minute incubations. It has been developed to detect IgM antibodies which are directed against Rubella virus, in human serum.

The Calibrators in the SeraQuest Rubella IgM test set have been assigned Index values based on an in-house standard. Test results are reported as Index values.

Principle:

Diluted samples are incubated in wells coated with Rubella virus antigen. Antibodies directed against rubella (if present) are immobilized in the wells. Residual sample is eliminated by washing and draining, and conjugate (enzyme-labeled antibodies to human IgM) is added and incubated. If IgM antibodies to Rubella are present, the conjugate will be immobilized in the wells. Residual conjugate is eliminated by washing and draining, and the enzyme substrate is added and incubated. In the presence of the enzyme, the substrate is converted to a yellow end-product which is read photometrically at 405 nm.

Intended Use:

For the qualitative detection of human IgM antibodies to Rubella virus in human serum by enzyme immunoassay, to aid in the diagnosis of Rubella infection. A positive result is presumptive for the detection of rubella antibodies and presumptive for the diagnosis of active or recent rubella infection. For manual use, or for use with the HyPrep System Plus. For In Vitro Diagnostic Use Only.

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Predicate device:

The SeraQuest Rubella IgM test has been shown to be substantially equivalent to the Diamedix Rubella IgM kit, Diamedix Corporation, Miami, FL.

Summary of technological characteristics:

<u>Characteristic</u>	<u>SeraQuest Rubella IgM</u>	<u>Diamedix Rubella IgM Microassay</u>
Description:	Enzyme Immunoassay	Enzyme Immunoassay
Intended Use:	The detection of IgM antibodies against Rubella virus in human serum.	The detection of IgM antibodies against Rubella virus in human serum.
Antigen Strain	HPV-77	Not stated in package insert
Solid Phase:	Plastic Microwell	Plastic Microwell
Number of Incubation Periods:	Three	Three
Sample Dilution:	1:26	1:41
Sample Volume:	100 µl	100 µl
Sample Pretreatment Duration:	None	None
Sample Incubation Duration:	30 minutes	30 minutes
Incubation Temperature:	Room temperature	Room temperature
Ezyme-labeled Conjugate:		
Antibody	Goat anti-human IgM	Goat anti-human IgM
Enzyme	Alkaline phosphatase	Alkaline phosphatase
Conjugate Volume:	100 µl	100 µl
Conjugate Incubation Duration:	30 minutes	30 minutes
Substrate:	p-Nitrophenyl phosphate	p-Nitrophenyl phosphate

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Substrate Volume:	100 μ l	100 μ l
Substrate Incubation Duration:	30 minutes	30 minutes
Stop Reagent:	0.5 M Trisodium phosphate	0.5 M Trisodium phosphate
Stop Reagent Volume:	100 μ l	100 μ l
Readout:	Spectrophotometric 405 nm	Spectrophotometric 405 nm

Summary of Clinical Testing:

Experimental Procedure

Ninty-one archival serum specimens including: 49 specimens from patient presenting with symptoms consistent with rubella infection and 42 specimens reported to be positive for IgM antibodies to rubella which were obtained from serum brokers, were tested at Quest International, Inc., concurrently by the SeraQuest Rubella IgM test and the Diamedix Rubella IgM Microassay. The assays were performed and interpreted according to the manufacturers package inserts. Specimens giving discordant results were tested with a second legally marketed device, along with a representative number of positive and negative samples which gave concordant results by both test methods.

Results and Conclusion

Of the 91 specimens tested, 46 were positive, and 40 were negative in both the SeraQuest and Diamedix tests (please see Table 1). Of the 5 remaining specimens, 2 specimens which were negative by the Diamedix test were positive by the SeraQuest test, and 3 specimens which were positive by the Diamedix test were negative in the SeraQuest test.

Excluding the equivocal results, the overall agreement between the SeraQuest Rubella IgM test, and the Diamedix Rubella IgM Microassay, was 97.7 percent.

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TABLE 1.

RESULTS OF SeraQuest RUBELLA IgM ASSAYS, AND DIAMEDIX RUBELLA IgM MICROASSAYS, OF 91 SERUM SPECIMENS. THE SPECIMENS INCLUDED: 49 SPECIMENS FROM PATIENTS PRESENTING WITH SYMPTOMS CONSISTENT WITH RUBELLA INFECTION, AND 42 SPECIMENS REPORTED TO BE POSITIVE FOR IgM ANTIBODIES TO RUBELLA, WHICH WERE OBTAINED FROM SERUM BROKERS. THESE TESTS WERE PERFORMED IN-HOUSE AT QUEST INTERNATIONAL, INC., MIAMI, FL.

Diamedix Rubella IgM	SeraQuest Rubella IgM		
	Positive	Equivocal	Negative
Positive	46	0	0
Negative	2	3	40

Agreement excluding equivocal results, 97.7 %



OCT 16 1998

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Robert A. Cort
Vice President, Quality Assurance
Quest International, Inc.
1938 N.E. 148th Terrace
North Miami, FL 33181

Re: K982281
Trade Name: SeraQuest Rubella IgM
Regulatory Class: III
Product Code: LFX
Dated: August 24, 1998
Received: August 31, 1998

Dear Mr. Cort:

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.

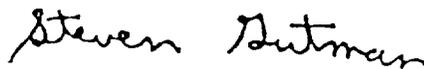
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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" (21 CFR 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 at (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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

APPENDIX 10

510(k) Number (if known): _____

Device Name: SeraQuest Rubella IgM

Indications For Use:

1. For the qualitative detection of IgM antibodies to Rubella in human serum by enzyme immunoassay, to aid in the diagnosis of Rubella infection.
2. A positive result is presumptive for the detection of anti-rubella antibodies and presumptive for the diagnosis of acute or recent rubella infection.
3. Useful for the above indications, with specimens obtained from women of childbearing age.
4. For manual use, or for use with the HyPrep System Plus semi-automated fluid handler.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Debois
 (Division Sign Off)
 Division of Clinical Laboratory Devices
 510(k) Number K982281

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)