

Spectral Diagnostics Inc.
Multiquant® Quantitative Myoglobin Test
510(k) Notification

PREMARKET NOTIFICATION 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Myoglobin is an oxygen-binding heme protein with a molecular weight of 17,800 daltons, normally found in cardiac and skeletal tissue which serves as an oxygen-storing pigment necessary for a high level of oxidative phosphorylation. It constitutes about 2% of the total muscle protein and is located in the cytoplasm of the cell. Cell injury or death during acute myocardial infarction (AMI) has been shown to release myoglobin into the blood. Blood myoglobin reaches the upper limit of normal approximately 2-3 hours after the onset of symptoms. The concentration of myoglobin has been shown to peak at 9-12 hours and to return to normal within 24-36 hours after an AMI.^{1,2} A number of reports have been published detailing the clinical utility of myoglobin in the early diagnosis and monitoring of AMI.³⁻⁶

The Spectral Diagnostics Multiquant® Quantitative Myoglobin Test is an automated latex immunoturbidometric method. The test utilizes a monoclonal antibody and a polyclonal antibody each covalently bound to polystyrenesupercarboxylated latex particles. When serum or plasma and assay buffer are combined with the latex particles, myoglobin in the specimen crosslinks adjacent latex beads and produces an increase in the turbidity of the solution. The turbidity, measured at 600nm, is proportional to the concentration of myoglobin present in the serum or plasma.

The safety and effectiveness of the Spectral Diagnostics Multiquant® Quantitative Myoglobin Test is demonstrated by its substantial equivalency to Dade-Behring Stratus® Myoglobin Fluorometric Assay. Both tests for myoglobin are used to measure myoglobin in serum and plasma and both use immochemical technologies. In a methods correlation against the Stratus® Myoglobin Fluorometric Assay the correlation coefficient was 0.99 and a regression equation of Multiquant® = 1.04(Stratus) + 0.0, N= 172, r = 0.99 , range = 7.6 to 496.3 ng/mL was obtained with serum samples. Within run precision and between run precision were 3.59% and 6.48% respectively for a sample containing 32.08 mg/mL myoglobin and 2.03% and 2.74% respectively for a sample containing 288.72 mg/mL.

References

1. Chapelle, J.P. et al., Serum myoglobin determinations in the assessment of acute myocardial infarction. *Eur.Heart Journal*. 3:122 (1982)
2. Kagen, L. et al., Myoglobinemia following myocardial infarction. *Am.J.Med.* 58:177 (1975)
3. Ohman, E.M. et al., Early detection of acute myocardial infarction: Additional diagnostic information from serum concentrations of myoglobin in patients without ST elevation. *Br.Heart J.* 63:335 (1990)
4. Mair, J. et al., Rapid diagnosis of myocardial infarction by immunoturbidimetric myoglobin measurement. *Lancet* 337:1343 (1991)
5. Tucker, J.F., et al., Value of serial myoglobin levels in the early diagnosis of patients admitted for acute myocardial infarction, *Ann.Emerg.Med.* 24:704 (1994)
6. Gibler, W.B., et al, Myoglobin as an early indicator of acute myocardial infarction. *Ann.Emerg.Med.* 16:851 (1987)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 7 1998

Joseph Laurino, Ph.D.
Director of Operations
Spectral Diagnostics Inc.
135-2 The West Mall
Toronto, Ontario
Canada M9C 1C2

Re: K982679
Multiquant® Quantitative Myoglobin Test
Regulatory Class: II
Product Code: DDR
Dated: July 29, 1998
Received: July 31, 1998

Dear Dr. Laurino:

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 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 (Pre-market 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 pre-market 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.

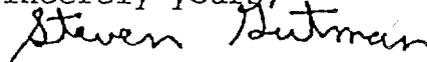
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (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

K 982679

510(k) Number (if Known) : ~~Not Known at this time~~

Device Name : Multiquant® Quantitative Myoglobin Test

Indications for Use:

The Multiquant® Quantitative Myoglobin Test is intended for use for as an *in vitro* diagnostic product to measure by immunochemical techniques the myoglobin (an oxygen storage protein found in muscle) in serum and plasma. Measurement of myoglobin aids in the rapid diagnosis of heart disease.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The Counter Use
(Optional Format 1-2-96)


(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K 982679