

OCT 4 1999

1992127

PREMARKET NOTIFICATION 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Troponin I (TnI) is part of the troponin complex which, together with tropomyosin, forms the main component that regulates the Ca^{+2} -sensitive ATP-ase activity of actomyosin in striated muscle (skeletal and cardiac)¹. Different isoforms of TnI exist in the skeletal and cardiac muscles (sTnI and cTnI, respectively) with distinct immunologic epitopes that allow the production of cardiac-specific TnI antibodies². Cardiac troponin-I has been established as a useful tool in the diagnosis of acute myocardial infarction (AMI)³⁻⁵. Cell injury from AMI has been shown to result in a level of blood troponin I above the upper limit of normal in approximately 4 to 6 hours after the onset of chest pain. Maximum concentrations are reached at 24 to 48 hours with the levels of troponin I remaining elevated for up to 14 days⁶.

The Spectral Diagnostics CardioQuant™ Troponin I Test is an automated latex immunoturbidometric method. The test utilizes monoclonal and polyclonal antibodies each covalently bound to polystyrene supercarboxylated latex particles. When serum or plasma and assay buffer are combined with the latex particles, troponin I in the specimen cross-links adjacent latex beads and produces an increase in the turbidity of the solution. The turbidity, measured at 600nm, is proportional to the concentration of troponin I present in the serum or plasma.

The safety and effectiveness of the Spectral Diagnostics CardioQuant™ Troponin I Test is demonstrated by its substantial equivalency to Dade-Behring Stratus® Troponin I Fluorometric Assay. Both tests for troponin I are used to measure the cardiac marker in serum and plasma and both use immunochemical technologies. In a methods correlation against the Stratus® Troponin I Fluorometric Assay the correlation coefficient was 0.87 and the regression equation of CardioQuant™ = 0.18(Stratus) + 0, N= 281, range = 0 to 35.4 ng/mL. was obtained with serum samples. Within assay precision and total assay precision were 4.0 % and 4.7% respectively for a sample containing 5.3 ng/mL troponin I and 2 % and 1.4 % respectively for a sample containing 16.7 ng/mL.

References

1. Mehegan, J.P. And Tobacman, L.S. Cooperative interaction between troponin molecules bound to the cardiac thin filament. *J.Biol.Chem.* 266:966 (1991)
2. Ebashi,S., Ca^{2+} and the contractile proteins. *J.Mol.Cell.Cardiol.* 16:129 (1984)
3. Bodor, S.G., et al., Development of monoclonal antibody for an assay of cardiac troponin I and preliminary results in suspected cases of myocardial infarction. *Clin.Chem.* 38:2203 (1992)
4. Adams, J.E., et al, Biochemical markers of myocardial injury. Is MB creatin kinase the choice for the 1990's. *Circulation* 88:750 (1993)
5. Hamm,C.W., Cardiac-specific Troponins in Acute Coronary Syndromes, in Heart Disease, a textbook of Cardiovascular Medicine, ed. Braunwald, E., W.B. Saunders Co. Update 3 (1977)
6. Hamm, C.W., et al., Emergency room triage of patients with acute chest pain by means of rapid testing for cardiac troponin T or troponin I. *New Eng.J.Med.* 337:1648 (1997)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 4 1999

Spectral Diagnostics Inc.
c/o Francee S. Boches, Ph.D.
Boches Consulting
5550 N.W. 102 Place
Miami, Florida 33178

Re: K992127
Trade Name: Cardioquant Troponin I Test
Regulatory Class: II
Product Code: MMI
Dated: September 9, 1999
Received: September 9, 1999

Dear Dr. Boches:

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.

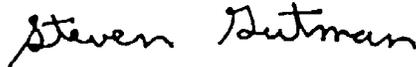
Page 2

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/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

Spectral Diagnostics Inc.
CardioQuant™ Troponin I Test
510(k) Notification

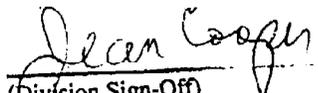
12992127

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

Device Name : CardioQuant™ Troponin I Test

Indications for Use:

The CardioQuant™ Troponin I Test is intended for use for as an *in vitro* diagnostic product to measure by immunochemical techniques the cardiac troponin I in serum and plasma. Measurement of troponin I aids in the rapid diagnosis of heart disease.


(Division Sign-Off)
Division of Clinical L
510(k) Number 12992127

(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)