

DEC - 8 1997

Summary of Safety and Effectiveness

As required by 21 CFR 807.92, the following 510(k) Summary is provided:

1. Submitters Information

Contact person: William J. Pignato
Director of Regulatory Affairs

Address: Chiron Diagnostics Corporation
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Medfield, MA 02052

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Date Summary Prepared: November 14, 1997

2. Device Information

Proprietary Name: Chiron Diagnostics ACS:180 Myoglobin
Common Name: Myoglobin Immunological test system
Device Classification: Class II, 21 CFR 866.5680

3. Predicate Device Information

Name: Stratus Myoglobin Fluorometric Enzyme
Immunoassay

Manufacturer: Dade International Inc.

4. Device Description

Myoglobin is a oxygen-binding, heme protein, found in cardiac and skeletal muscle. Myoglobin is noted for its rapid release into the circulation following tissue injury. Elevated levels of myoglobin can be found in conditions of muscle damage, such as acute and chronic skeletal muscle disease, renal failure, myocarditis, open-heart surgery, and after heavy exercise.

Myoglobin releases into the circulation as early as 2 to 4 hours after cell damage, peaks at between 9 and 12 hours, and returns to normal within 24 to 36 hours. In the absence of skeletal muscle trauma, myoglobin has been used as an early indicator of myocardial infarction, and therefore as a rule out indicator.

Myoglobin has a negative predictive value of 99%, which improves the rule out capabilities of the emergency department and helps reduce the number of patients inappropriately admitted to the Coronary Care Units with symptoms atypical of acute

myocardial infarction. When used in combination with other cardiac markers such as CK-MB or cTnI, the ACS myoglobin assay is a valuable diagnostic tool to be used in the early evaluation of the potential acute myocardial infarction patient.

5. Statement of Intended Use

The intended use of Chiron Diagnostics ACS:180 Myoglobin Assay is for the quantitative determination of Myoglobin in serum or plasma and as an aid in the diagnosis of acute myocardial infarction using the Chiron Diagnostics ACS Automated Chemiluminescence Systems.

6. Summary of Technological Characteristics

The Chiron Diagnostics ACS:180 Myoglobin assay is a two-site sandwich immunoassay using direct chemiluminometric technology, which uses constant amounts of two antibodies. The first antibody, in the Lite Reagent, is a polyclonal goat anti-myoglobin antibody labeled with acridinium ester. The second antibody, in the Solid Phase, is a monoclonal mouse anti-myoglobin antibody covalently coupled to paramagnetic particles.

6. Performance Characteristics

Expected Results

To confirm the ACS:180 Myoglobin reference range 703 serum and plasma samples from apparently healthy individuals were analyzed. Based on a central 95% interval, the following reference ranges were established:

Sample Category	N	Average (ng/mL) (µg/L)	Range (ng/mL)(µg/L)
Male	353	47.9	5.1—90.7
Female	350	32.7	10—65.3

As with all in vitro diagnostic assays, each laboratory should determine its own reference range(s) for the diagnostic evaluation of patient results.

Sensitivity and Assay Reportable Range

The ACS:180 Myoglobin assay measures myoglobin concentrations up to 1000 ng/mL(µg/L) with a minimum detectable concentration (analytical sensitivity) of ≤ 10

ng/mL(μ g/L). Analytical sensitivity is defined as the concentration of myoglobin that corresponds to the RLUs that are two standard deviations greater than the mean RLUs of 20 replicate determinations of the Myoglobin zero standard.

Method Comparison

For 123 samples in the range of 27 to 957 ng/mL(μ g/L) the relationship between the ACS:180 Myoglobin assay and an alternate myoglobin EIA method is described by the equation:

$$\text{ACS:180 Myoglobin} = 1.06 \times (\text{alternate EIA method}) - 4.6 \text{ ng/mL}(\mu\text{g/L})$$

Correlation coefficient (r) = 0.99

Precision

Eight samples were assayed 6 times in 6 assays, on each of 4 systems (n =144 for each sample), over a period of 3 days. Total precision (% CV) range between 4.2 to 5.3.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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William J. Pignato
Director of Regulatory Affairs
Chiron Diagnostics
63 North Street
Medfield, Massachusetts 02052-1688

Re: K974325
Chiron Diagnostics ACS:180® Myoglobin Assay
Product Code: DDR
Regulatory Class: II
Dated: November 14, 1997
Received: November 18, 1997

Dear Mr. Pignato:

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.

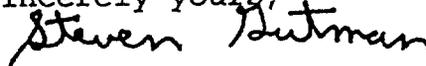
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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

