JUN 2 8 2002

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K021229

Submitter's Name and Address

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (952)368-1611
Fax: (952)368-7610
Contact: Bruce Backlund

Date Prepared: April 17, 2002

Device Names

Proprietary Name:	Myoglobin and Myoglobin Calibrators on the Access® Immunoassay Systems
Common Name:	Myoglobin Enzyme Immunoassay
Classification Name:	Myoglobin, Antigen, Antiserum, Control

Predicate Device

Access® Myoglobin
Beckman Coulter Inc.
Chaska, MN 55416

510(k) Number: K000196

Device Description

The Access Myoglobin reagents, Myoglobin calibrators, the Access Immunoassay Analyzer and the Access 2 Immunoassay Analyzer comprise the Access Immunoassay Systems for the quantitative determination of cardiac Myoglobin in human serum and plasma.

Intended Use

The Access Myoglobin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac Myoglobin levels in human serum and plasma using the Access Immunoassay Systems.

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Comparison of Technological Characteristics

Parameter	Access New Myoglobin	Access Current BCI Myoglobin
Intended Use	For the quantitative determination of Myoglobin levels in human serum and plasma	For the quantitative determination of Myoglobin levels in human serum and plasma
Assay Principles	A two-site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with mouse monoclonal anti-myoglobin-alkaline phosphatase conjugate, mouse monoclonal anti-myoglobin-biotin conjugate, and paramagnetic particles coated with goat anti-biotin.	A two-site immunoenzymatic ("sandwich") assay. A sample is added to a reaction vessel with mouse monoclonal anti-myoglobin-alkaline phosphatase conjugate, and paramagnetic particles coated with mouse monoclonal anti-myoglobin.
Solid Support	Paramagnetic Particles	Paramagnetic Particles
Detection System	Utilizes dioxetane-based chemiluminescent substrate; Measures light production from a chemiluminescent reaction	Utilizes dioxetane-based chemiluminescent substrate; Measures light production from a chemiluminescent reaction
Calibrators	Liquid calibrators (frozen) prepared from buffered bovine serum albumin matrix with human cardiac Myoglobin at specified levels	Liquid calibrators prepared from buffered bovine protein matrix and human skeletal Myoglobin at specified levels

Summary of Analytical Studies

Precision: Within run imprecision ranged from 1.58%CV to 2.20%CV, between-run imprecision ranged from 2.34%CV to 4.24%CV and total imprecision ranged from 3.03%CV to 4.54%CV.

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Analytical Sensitivity: The lowest detectable level of Myoglobin distinguishable from zero (Access Myoglobin calibrator S0) with 95% confidence is <1.0 ng/mL.

Dilution Recovery (Linearity): Linearity studies performed by diluting lithium heparin plasma samples with Access Sample Diluent A provided an average recovery of the samples of 93%, with individual sample average recoveries ranging from 86% to 100%.

Method Comparison: A comparison of cardiac Myoglobin values from 148 samples, ranging from 0.00 to 3,227.80 ng/mL, run with both the Access New Myoglobin assay and the Current BCI Myoglobin assay demonstrated good agreement with the following statistical data:
Y =1.113X + 15.903 R=0.997

Matched Sample Comparison: No clinically significant bias was noted between lithium heparin plasma and sodium heparin plasma or serum samples. A bias was noted when using EDTA plasma samples. (Y= 0.8925X + 5.0115 R=0.9981)*.

Analytical Specificity: There was no significant interference from therapeutic drugs or biological substances. None of the RF samples or the HAMA samples tested above the Upper Reference Limit (URL). Two heterophile samples tested above the URL. Of this group, both heterophile samples tested did not prove to be blocked by treatment with HBT (heterophile blocking tubes).

Stability: Myoglobin reagents are stable for 56 days after opening and calibrators are stable for 60 days after opening. The calibration curve is stable for 56 days.

Reference Intervals: Separate reference limits were computed for LHS (Lithium Heparin, Serum) and EDTA assays for males and females.

The Lithium Heparin and Serum (LHS) upper reference limit (97.5th percentile) was determined to be 66 ng/mL for Females and the 106 ng/mL for Males. The EDTA upper reference limit (97.5th percentile) was determined to be 58 ng/mL for females and 91 ng/mL for males

Conclusion
Access Myoglobin and Myoglobin calibrators on the Access Immunoassay Systems are substantially equivalent to another test currently in commercial distribution for the measurement of Myoglobin.

* See Reference Interval section

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Bruce Backlund
Senior Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

JUN 2 8 2002

Re: k021229
Trade/Device Name: Myoglobin ™ and Myoglobin Calibrators on the Access® Immunoassay System
Regulation Number: 21 CFR 866.5680; 21 CFR 862.1150
Regulation Name: Myoglobin immunological test system; Calibrator
Regulatory Class: Class II
Product Code: DDR; JIS
Dated: April 17, 2002
Received: April 18, 2002

Dear Mr. Backlund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 International and Consumer 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 Gutman

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 STATEMENT

510(k) Number (if known): K021229

Device Name: Myoglobin™ and Myoglobin Calibrators on the Access® Immunoassay System

Indications For Use:

Measurement of myoglobin aids in the rapid diagnosis of heart and renal disease.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021229

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The Counter Use_
(Per 21 CFR 801.109)

(Optional Format 1-2-96)