



JAN 17 2003

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:

K030012

Submitter's Name and Address

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (952)368-1323
Fax: (952)368-7610
Contact: Brent Taber

Date Prepared: December 31, 2002

Device Names

Proprietary Name: CK-MB and CK-MB Calibrators on the Access®
Immunoassay Systems

Common Name: CK-MB Enzyme Immunoassay

Classification Name: Fluorometric Method, CPK or Isoenzymes

Predicate Device

Access® CK-MB Assay for Use on the Access® Immunoassay Analyzer
Beckman Coulter, Inc.
Chaska, MN 55318

510(k) Number: K000716



Device Description

The Access CK-MB reagents, calibrators, and the Access Immunoassay Analyzers (Access, Access 2, and Synchron LXi 725) comprise the Access Immunoassay Systems for the quantitative determination of CK-MB in human serum and plasma.

Intended Use

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

Comparison of Technological Characteristics

Attribute	Current Access CK-MB	Modified Access CK-MB
Intended Use	For the measurement of CK-MB in human serum and plasma	For the measurement of CK-MB in human serum and plasma
Assay Principles	Utilizes the binding of CK-MB to specific monoclonal antibodies in a two site "sandwich" immunoassay; Utilizes alkaline phosphatase enzyme conjugated to monoclonal antibody	Utilizes the binding of CK-MB to specific monoclonal antibodies in a two site "sandwich" immunoassay; Utilizes alkaline phosphatase enzyme conjugated to monoclonal antibody
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 prepared from buffered bovine serum albumin matrix with recombinant CK-MB at specified levels	Liquid calibrators prepared from buffered bovine serum albumin matrix with recombinant CK-MB at specified levels



Summary of Analytical Studies

Precision: Within run imprecision ranged from 1.15%CV to 2.32%CV, between-run imprecision ranged from 1.47%CV to 2.89%CV and total imprecision ranged from 2.66%CV to 3.54%CV at levels ranging between 4.5 and 172.3 ng/mL.

Analytical Sensitivity: The lowest detectable level of CK-MB distinguishable from zero (Access CK-MB calibrator S0) with 95% confidence is <0.1 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 102%, with individual sample average recoveries ranging from 95% to 109%.

Method Comparison: A comparison of CK-MB values from 120 samples, ranging from 0.6 to 208.7 ng/mL (modified CK-MB), run with both the modified Access CK-MB assay and the current CK-MB assay demonstrated good agreement with the following statistical data: $y = 0.879x + 0.907$, $r = 0.997$.

Analytical Specificity: There was no significant interference from therapeutic drugs, biological substances, or heterophile samples. There was no significant cross-reactivity with other creatine kinase isoenzymes (CK-BB or CK-MM).

Stability: CK-MB 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 intervals were calculated for lithium heparin plasma and serum, and EDTA plasma. The lithium heparin plasma and serum reference interval (95% central fraction) is 0.6 – 6.3 ng/mL. The EDTA plasma reference interval (95% central fraction) is 0.5 – 5.0 ng/mL.



Conclusion

CK-MB and CK-MB Calibrators on the Access Immunoassay Systems is substantially equivalent to Access® CK-MB Assay for Use on the Access® Immunoassay Analyzer for the measurement of CK-MB in human serum and plasma.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 17 2003

Mr. Brent Taber
Senior Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine
Chaska, MN 55318-1084

Re: k030012
Trade/Device Name: CK-MB and CK-MB Calibrators on the Access[®] Immunoassay
Systems
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatinase or isoenzymes test system.
Regulatory Class: Class II
Product Code: JHX, JIS
Dated: December 31, 2002
Received: January 2, 2003

Dear Mr. Taber:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

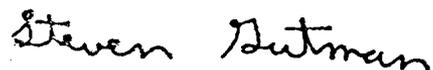
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

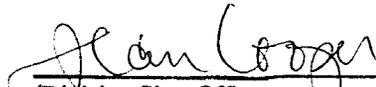
Enclosure

510(k) Number (if known): K030012

Device Name: CK-MB and CK-MB Calibrators on the Access® Immunoassay Systems

Indications For Use:

The Access CK-MB assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CK-MB levels in human serum and plasma using the Access Immunoassay Systems. Measurement of creatine kinase is used in the diagnosis and treatment of myocardial infarction.



 (Division Sign-Off)
 Division of Clinical Laboratory Devices
 510(k) Number K030012

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
 (Per 21 CFR 801.109)

OR

Over-The Counter Use _____

(Optional Format 1-2-96)