JAN 14 2000

K994439

510(k) Summary
January 11, 2000

Applicant's Name and Address

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

Contact Person: Michele S. Gust

Device Name

Trade Name - Access® CK-MB Reagents on the Access® Immunoassay System
Common Name – Access® CK-MB
Classification name – Fluorometric Method, CPK or Isoenzymes

Device Description

The Access CK-MB assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of CK-MB levels in human serum or plasma, using the Access Immunoassay Systems.
The Access CK-MB reagents consist of reagent packs, calibrators, controls substrate and wash buffer. The Access CK-MB assay, CK-MB calibrators, CK-MB QC along with the Access System Wash Buffer and Substrate are designed for use with the Access Immunoassay Analyzer in a clinical laboratory setting.

Intended Use

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

Comparison of Technological Characteristics

The Access CK-MB assay and the predicate device are contain a solid phase of particles ~~and use a labeled antibody conjugated to alkaline phosphatase.~~ The calibrators consist of 6 levels in which the analyte is human CK-MB. Both of these devices are intended to measure CK-MB in human serum and plasma.

Summary of Studies

Precision:
Within-run, between-run, and total imprecision were less than 10% CV.
Spiking and Dilution Recovery:
Linearity studies performed by diluting one human sample containing CK-MB with CK-MB Calibrator S0 yields an average recovery of 95.7%.
Correlation:
A comparison of the Access CK-MB assay and the predicate device gives the following statistical data—n=356, r=0.984, y=0.836x + 0.662.
A comparison of CK-MB values of paired serum and plasma(EDTA) run in the Access CK-MB assay gives the following statistical data—n=48, r=0.998, y=1.009x + 1.119.
A comparison of CK-MB values of paired serum and plasma (heparin) run in the Access CK-MB assay gives the following statistical data—n=84, r=0.999, y=1.015x – 0.631.
Analytical Sensitivity:
The lowest detectable level of CK-MB distinguishable for zero (CK-MB S0 calibrator) with 95% confidence is 0.3 ng/ml.

Conclusion

The Access CK-MB reagents when used with the Access Immunoassay Analyzer are substantially equivalent to another test currently in commercial distribution for the measurement of CK-MB.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 14 2000

Ms. Michele S. Gust
Senior Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

Re: K994439
Trade Name: Access® CK-MB Assay on the Access® Immunoassay Analyzer
Regulatory Class: II
Product Code: JHX
Dated: December 22, 1999
Received: December 23, 1999

Dear Ms. Gust:

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.

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 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

510(k) Number (if known):

Device Name: Access® CK-MB ~~Reagents~~ Assay on the Access Immunoassay Analyzer

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 or plasma, using the Access Immunoassay System. Measurements of creatine phosphokinase and its isoenzymes are used in the diagnosis and treatment of myocardial infarction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Labor...
510(k) Number K994439

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