SEP 2 7 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: K021814

Submitter's Name and Address

Beckman Coulter, Inc.
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Contact: Brent Taber

Date Prepared: May 31, 2002

Device Names

Proprietary Name: AccuTnI™ and AccuTnI Calibrators on the Access® Immunoassay Systems
Common Name: Troponin I Enzyme Immunoassay
Classification Name: Immunoassay, Troponin Subunits

Predicate Device

AccuTnI™ and AccuTnI Calibrators on the Access® Immunoassay System
Beckman Coulter, Inc.
Chaska, MN 55318

510(k) Number: K010429

Device Description

The Access AccuTnI reagents, AccuTnI calibrators, and the Access and Access 2 Immunoassay Analyzers comprise the Access Immunoassay Systems for the quantitative determination of cardiac troponin I in human serum and plasma.

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Intended Use

The Access AccuTnI assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis and treatment of myocardial infarction and cardiac muscle damage.

Cardiac troponin I determination aids in the risk stratification of patients with unstable angina or non-ST segment elevation acute coronary syndromes with respect to relative risk of mortality, myocardial infarction, or increased probability of ischemic events requiring urgent revascularization procedures.

Summary of Analytical Studies

No changes have been made to the assay reagents submitted under K010429. The 510(k) Summary for K010429 summarizes analytical studies including precision, analytical sensitivity, dilution recovery (linearity), method comparison, matched sample comparison, analytical specificity, stability, reference intervals, and equimolarity.

Summary of Clinical Performance

Relative Risks (RR), Odds Ratios (OR), and clinical sensitivity and specificity were calculated relative to three Access AccuTnI cutoffs (97.5^{TH} and 99^{TH} percentiles of the reference range, and the median concentration at 10% CV imprecision), three follow-up periods (30 days, 42 days, and 10 months), and two endpoints (double composite endpoint consisting of death or myocardial infarction and triple composite endpoint consisting of death or myocardial infarction or urgent revascularization).

At the 97.5^{TH} percentile of the reference range, relative risks and odds ratios for the double and triple composite endpoints ranged from 1.68 to 3.61 for all three follow-up periods. All relative risks and odds ratios were statistically significant for both composite endpoints and the three follow-up periods.

At the 99^{TH} percentile of the reference range, relative risks and odds ratios for the double and triple composite endpoints ranged from 1.58 to 3.18 for all three follow-up periods. All relative risks and odds ratios were statistically significant for both composite endpoints and the three follow-up periods.

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At the median concentration at 10% CV imprecision, relative risks and odds ratios for the double and triple composite endpoints ranged from 1.62 to 3.60 for all three follow-up periods. All relative risks and odds ratios were statistically significant for both composite endpoints and the three follow-up periods.

The data demonstrate that the Access AccuTnI assay can be utilized to stratify patients for potential adverse cardiac events (double and triple composite endpoints) using three cutoffs at three follow-up periods.

Conclusion

Access AccuTnI and AccuTnI calibrators on the Access Immunoassay Systems, with the addition of a risk stratification indication for use to the intended use, is substantially equivalent to Access AccuTnI and AccuTnI calibrators on the Access Immunoassay System with indications as an aid in the diagnosis and treatment of myocardial infarction and cardiac muscle damage (K010429).

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 7 2002

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

Re: k021814
Trade/Device Name: AccuTnI™ and AccuTnI Calibrators on the Access® Immunoassay Systems
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase ot isoenzymes test system
Regulatory Class: Class II
Product Code: MMI
Dated: August 15, 2002
Received: August 16, 2002

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 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 Page ___ of ___

510(k) Number (if known): K021814

Device Name: AccuTnI™ and AccuTnI Calibrators on the Access® Immunoassay Systems

Indications For Use:

The Access AccuTnI assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis and treatment of myocardial infarction and cardiac muscle damage.

Cardiac troponin I determination aids in the risk stratification of patients with unstable angina or non-ST segment elevation acute coronary syndromes with respect to relative risk of mortality, myocardial infarction, or increased probability of ischemic events requiring urgent revascularization procedures.

Sean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021814

(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)