1.4 510(K) Summary

MAY 0 6 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.

510(k) Number K03 1270 **Date Prepared: April 17, 2003**

Submitter	*Contact Person*
Beckman Coulter, Inc 1000 Lake Hazeltine Drive Chaska, MN 55318	Lynn Weist Staff Regulatory Affairs Specialist Phone: 952-368-1271 Fax: 952-368-7710

General Information

Proprietary Name	Access® CEA Reagents on the Access® Immunoassay Systems
Classification Name	Carcinoembryonic Antigen (CEA) Immunological Test System for Management of Cancers
Device Class	Class II
Legally Marketed (Unmodified) Device	Access® CEA Reagents on the Access® Immunoassay Analyzer (K981985, cleared 09/24/98; K991707, cleared 06/01/99; Access 2 Add-to-File Letter, dated 04/24/01)

Device Description

The Access® CEA reagents consist of reagent packs, calibrators, bi-level controls, substrate and wash buffer.

Intended Use

The Access CEA assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Carcinoembryonic Antigen (CEA) levels in human serum, using the Access Immunoassay Systems. CEA measured by the Access Immunoassay Systems is used as an aid in the management of cancer patients in whom changing CEA concentrations have been observed.

510(k) Summary

Description of the Modification to the Legally Marketed Device

The modification to the Access CEA reagents is to add a new instrument platform, the Beckman Coulter UniCel™ DxI 800 Access® Immunoassay System, to the family of Access Immunoassay Systems. The DxI System is a new model within the same model series of Access Immunoassay Systems manufactured and distributed by Beckman Coulter, Inc. The DxI System was cleared for marketing by FDA on January 28, 2003, K023764.

The DxI uses the same Access CEA reagents and calibrators, packaged the same as for the Access 2 System. The formulations of the substrate and wash buffer used with the Access CEA assay are unchanged. There are no changes to the intended uses, technical specifications or final performance specifications and claims for the assay.

Supporting Data

In order to demonstrate that the Access CEA assay on the DxI system is substantially equivalent to the Access CEA assay on the Access 2 system, method comparison, precision and analytical sensitivity studies were conducted. The Access CEA assay met the established acceptance criteria for method comparison, precision and analytical sensitivity.

Conclusion

The information provided in this submission supports a substantial equivalence determination, and therefore, 510(k) premarket notification clearance of the Access CEA Reagents on the UniCel DxI 800 Access Immunoassay System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Lynn Weist
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

MAY 0 6 2003

Re: k031270
Trade/Device Name: Access® CEA Reagents on the Access® Immunoassay Systems
Regulation Number: 21 CFR § 866.6010
Regulation Name: System Test, Carcinoembryonic Antigen
Regulatory Class: II
Product Code: DHX
Dated: April 17, 2003
Received: April 22, 2003

Dear Ms. Weist:

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). 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). You may obtain other general information on your responsibilities under the Act 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
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

1.3 Indications for Use Statement

510(k) Number (if known): K031270 **PAGE 1 OF 1**

Device Name: Access® CEA Reagents on the Access® Immunoassay Systems

Indications for Use:

The Access CEA assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Carcinoembryonic Antigen (CEA) levels in human serum, using the Access Immunoassay Systems. CEA measured by the Access Immunoassay Systems is used as an aid in the management of cancer patients in whom changing CEA concentrations have been observed.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

F. Reeves for J. Bertista

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K031270

Prescription Use ✓ OR Over-the-Counter Use _____
(per 21 CFR 801.109) (Optional Format 1-2-96)