Section 1 D: SUMMARY OF SAFETY AND EFFECTIVENESS FOR THE ACCESS® CEA ASSAY

1. 0 General Information

Device Generic Name:	Carcinoembryonic Antigen (CEA) Immunological Test System for Management of Cancers
Device Trade Name:	Access® CEA Reagents for use on the Access® Immunoassay Analyzer
Device Class:	Class II
Applicant's Name and Address:	Beckman Coulter, Inc. Immunodiagnostics Development Center 1000 Lake Hazeltine Drive Chaska, MN 55318
Date:	May 18, 1999

2.0 Legally Marketed Device

The Modified Access® CEA Immunoassay claims substantial equivalence to the Access® CEA Immunoassay currently in commercial distribution.

FDA 510(k) Number K981985

3.0 Device Description

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

- The Access® CEA reagent packs consist of paramagnetic particles coated with monoclonal (mouse) anti-human CEA antibodies in Tris buffered saline, sample diluent, monoclonal anti-human CEA-alkaline phosphatase conjugate in phosphate buffered saline, bovine serum albumin (BSA) and preservatives.
- The Access® CEA calibrators consist of multi-point calibrators for use with the Access CEA assay. The calibrator vials contain zero and approximately 1, 10, 100, 500, and 1000 ng/ml purified CEA, respectively, in a phosphate buffered BSA matrix with preservatives.
- The Access® CEA QC controls consist of approximately 3 ng/ml and 300 ng/ml of human CEA in a phosphate buffered BSA matrix with preservatives.
- The Access® substrate, Lumi-Phos* 530, is a dioxetane-based chemiluminescent substrate.
- The Access® wash buffer consists of Tris buffered saline containing surfactant and preservatives.

4.0 Principles of the Procedure

The Access® CEA assay is a two-site immunoenzymatic "sandwich" assay using two mouse monoclonal anti-CEA antibodies (MAb) which react with different epitopes of CEA. A sample is added to a reaction vessel, along with the first anti-CEA MAb-alkaline phosphatase conjugate and the second anti-CEA MAb bound to paramagnetic particles. The incubation is followed by a magnetic separation and washing. A chemiluminescent substrate, Lumi-Phos* 530, is added to the reaction vessel and light generated by the reaction is measured with a luminometer. The light production is proportional to the concentration of CEA in the sample. The amount of analyte in the sample is determined by means of a stored, multi-point calibrator curve.

5.0 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 System. CEA measured by the Access Immunoassay System is used as an aid in the management of cancer patients in whom changing CEA concentrations have been observed.

6.0 Description of the Modification to the Legally Marketed Device

The Access CEA assay has been re-calibrated in order to improve correlation with another commercially available device around the critical decision point of 5.0 ng/ml. There has been no change to the formulation or function of the product. The design change involves a reduction in calibrator mass with no change in labeled calibrator values. Insert changes have been made to reflect results from completed validation studies.

DEPARTMENT OF HEALTH & HUMAN SERVICES

JUN 1 1999

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Angela Byland
Regulatory Specialist
BECKMAN COULTER, INC.
1000 Lake Hazeltine Drive
Chaska, MN 55318

Re: K991707
Trade Name: Access® CEA Reagents for use on the Access® Immunoassay Analyzer
Regulatory Class: II
Product Code: DHX
Dated: May 18, 1999
Received: May 19, 1999

Dear Ms. Byland:

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

Section 1 C: **INDICATIONS FOR USE STATEMENT**

510(k) Number: ~~K981885~~ K991707

Device Name: Access® CEA Reagents for use on the Access® Immunoassay Analyzer

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 System. CEA measured by the Access Immunoassay System 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)

Peter E Mahan

(Division Sign-Off)
Division
510(k) Number K991707

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

(Optional Format 1-2-96)