SEP 24 1998

K 981985

510(k) Summary of Safety and Effectiveness

1. General Information

Device Generic Name:	Carcinoembryonic Antigen (CEA) Immunological Test System for Management of Cancers
Device Trade Name:	ACCESS® CEA Assay
Applicant's Name and Address:	Beckman Coulter, Inc. 1000 Lake Hazeltine Drive Chaska, MN 55318
Date:	June 4, 1998

2. Predicate Device

Abbott IMx CEA Microparticle Enzyme Immunoassay
Abbott Laboratories
One Abbott Park Road
Abbott Park, IL 60064-3500

PMA Number: P830066

3. Device Description

The ACCESS CEA Immunoassay Reagents and the ACCESS Immunoassay Analyzer comprise the ACCESS Immunoassay System for the quantitative determination of CEA in human serum.

4. Indications for Use

The ACCESS CEA Immunoassay is a paramagnetic particle chemiluminescent immunoassay for the quantitative determination of carcinoembryonic antigen (CEA) in human serum using the ACCESS Immunoassay System. CEA, measured by the ACCESS CEA Immunoassay, is intended for use as an aid in the management of cancer patients.

5. Comparison of Technological Characteristics

Both the ACCESS CEA Immunoassay and the Abbott IMx CEA assay quantitatively measure serum CEA by means of simultaneous immunoassays utilizing the binding of CEA to monoclonal antibodies specific to epitopes on the CEA molecule. Both systems utilize liquid multi-point calibrators.

The ACCESS CEA Immunoassay Reagents are designed for use on the ACCESS Immunoassay Analyzer, a fully automated random access system, with up to 24 different reagents on board. The Abbott IMx Immunoanalyzer is an automated batch mode system in which a single analyte is assayed at one time. The ACCESS Immunoassay Analyzer uses magnetic particle solid phase enzyme immunoassays with chemiluminescent measurement, while the Abbott IMx CEA Immunoassay uses a glass-fiber matrix as the solid phase with a fluorescent detection method.

6. Summary of Studies

Correlation: A comparison of CEA values from 146 samples, ranging from 0 to 1000 ng/ml, run with both the ACCESS CEA Immunoassay and the Abbott IMx CEA Immunoassay demonstrated very good agreement with the following statistical data: $r = 0.97$; $y = 1.02x + 1.76$.

Expected Range: In a population of 234 apparently healthy males and females, 98.7% had CEA values of 5.0 ng/ml or less, with the remaining 1.3% having values in the 5.1 to 10.0 ng/ml range.

Monitoring Data: Longitudinal serum samples from previously diagnosed cancer patients were compared using the ACCESS CEA and IMx CEA assays. The monitoring patient data demonstrate that the Access CEA results are highly concordant to both the IMx CEA results and the concurrent clinical assessments.

Recovery: Linearity studies performed by diluting human serum samples with ACCESS CEA Sample Diluent provided an average recovery of 99.9%, with sample mean recoveries ranging from 91.1 to 109.1%. Recovery of exogenous CEA spiked into serum samples resulted in an overall mean recovery of 103.0%, with mean recoveries ranging from 99.0 to 106.2%.

Precision: Within-run, between-run and total imprecision of the Access CEA immunoassay were less than 5% when tested at concentrations between 5.0 and 500 ng/ml.

Specificity: There was no significant interference from CEA-like antigens (NCA, NCA-2, NCA-50 and NFA-1), potential sample contaminants (albumin, bilirubin, HAMA, hemoglobin, lipemia and rheumatoid factor), and therapeutic agents (bleomycin-, cisplatin, cyclophosphamide, doxorubicin, fluorouracil, leucovorin, methotrexate, mitomycin, tamoxifen, vinblastine, and vincristine).

Hook Effect: There was no hook effect observed at CEA concentrations up to 100,000 ng/ml.

Analytical Sensitivity: The lowest level of detection of CEA distinguishable from zero (ACCESS CEA Calibrator S0) with 95% confidence is 0.1 ng/ml.

7. Conclusion

The ACCESS CEA Immunoassay Reagents, when used in conjunction with the ACCESS Immunoassay Analyzer, are substantially equivalent to the Abbott IMx CEA Immunoassay. The ACCESS CEA Immunoassay is appropriate for monitoring patients with cancer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 24 1998

Ms. Ellen Voss
Regulatory Affairs
Beckman Coulter
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

Re: K981985/S1
Trade Name: ACCESS® CEA Assay
Regulatory Class: II
Product Code: DHX
Dated: July 31, 1998
Received: July 31, 1998

Dear Ms. Voss:

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.

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: ACCESS® CEA

Indications For Use:

The ACCESS® CEA assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Carcinoembryonic antigen (CEA) in human serum using the ACCESS Immunoassay System. CEA measured by the ACCESS CEA Immunoassay, is used as an aid in the management of cancer patients.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Madsen

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981985

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

(Optional Format 1-2-96)