K981354

MAY 1 1998

510(k) Summary of Safety and Effectiveness

1. General Information

Device Generic Name:	Alpha-fetoprotein (AFP) Immunological Test System for the Management of Nonseminomatous Testicular Cancer
Device Trade Name:	ACCESS® AFP Assay
Applicant's Name and Address:	Beckman Instruments, Inc. 1000 Lake Hazeltine Drive Chaska, MN 55318
Date:	April 13, 1998

2. Predicate Device

Abbott IMx AFP Immunofluorometric Assay
Abbott Laboratories
One Abbott Park Road
Abbott Park, IL 60064-3500

PMA Number: P820060

3. Device Description

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

4. Indications for Use

The ACCESS AFP Immunoassay is a paramagnetic particle chemiluminescent immunoassay for the quantitative determination of alpha-fetoprotein (AFP) in human serum using the ACCESS Immunoassay System. AFP, measured by the ACCESS AFP Immunoassay, is intended for use as an aid in the management of patients with nonseminomatous testicular cancer.

5. Comparison of Technological Characteristics

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

The ACCESS AFP Immunoassay Reagents are designed for use on the ACCESS Immunoassay Analyzer, a fully automated random access system, while the Abbott IMx AFP assay is a batch mode system. The ACCESS Immunoassay Analyzer uses magnetic particle solid phase enzyme immunoassays with chemiluminescent detection, while the Abbott IMx AFP assay uses a glass fiber solid phase and fluorescent detection. The Access AFP assay can measure samples with AFP concentrations up to 3000 ng/ml without prior dilution while the IMx AFP assay requires dilution of samples with AFP concentrations of greater than 350 ng/ml. The ACCESS Immunoassay Analyzer stores reagents on board for up to 24 different analytes and has 28 day calibration curve stability, while Abbott IMx AFP assay is an individual analyte reagent kit.

6. Summary of Studies

Correlation: A comparison of AFP values from 170 samples, ranging from 0.90 to 3000 ng/ml, run with both the ACCESS AFP Immunoassay and the Abbott IMx AFP assay demonstrated very good agreement with the following statistical data: $r = 0.99$; $y = 0.91x + 3.86$.

Expected Range: In a population of 177 apparently healthy males and females, 98.9% had AFP values of 9.0 ng/mL or less, with the remaining 1.1% having values in the 9.1 to 15 ng/mL range.

Monitoring Data: Longitudinal samples from previously diagnosed nonseminomatous testicular cancer patients were compared using the ACCESS AFP and Abbott IMx AFP assays. The monitoring patient data demonstrate that the ACCESS AFP results are highly concordant to both the IMX AFP results and the concurrent clinical assessment.

Recovery: Linearity studies performed by diluting human serum samples with ACCESS AFP Sample Diluent provided recoveries ranging from 96 to 110%. Recovery of exogenous AFP (from cord serum) spiked into serum samples resulted in an average recovery of 99%, with individual recoveries ranging from 90 to 108%.

Precision: The ACCESS AFP assay exhibits assay imprecision of less than 6% for AFP concentrations ranging from approximately 6.5 to 1680 ng/ml.

Specificity: There was no significant interference from potential biological substances, therapeutic drugs or other cross-reacting substances.

Analytical Sensitivity: The lowest detectable level of AFP distinguishable from zero (ACCESS AFP Calibrator S0) with 95% confidence is 0.5 ng/ml.

7. Conclusion

The ACCESS AFP Immunoassay Reagents, when used in conjunction with the ACCESS Immunoassay Analyzer, are substantially equivalent to another commercially available immunoassay for the measurement of serum AFP. The ACCESS AFP Immunoassay is appropriate for monitoring patients with nonseminomatous testicular cancer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 1998

Ms. Ellen Voss
Regulatory Affairs
Beckman Instruments, Inc.
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318

Re: K981354
Trade Name: ACCESS® AFP Assay
Regulatory Class: II
Product Code: LOJ
Dated: April 13, 1998
Received: April 14, 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 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 requirement, 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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/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® AFP

Indications For Use:

The ACCESS® AFP assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of alpha-fetoprotein (AFP) in human serum using the ACCESS Immunoassay System. AFP measured by the ACCESS AFP Immunoassay, is used as an aid in the management of patients with nonseminomatous testicular cancer.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maheux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K981354

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

(Optional Format 1-2-96)