JUN 12 1998

K981864

510(k) Summary of Safety and Effectiveness

1. General Information

Device Generic Name:	Single (Specified) Analyte Controls, Assayed Control
Device Trade Name:	Access AFP QC
Applicant's Name and Address:	Beckman Coulter, Inc. 1000 Lake Hazeltine Drive Chaska, MN 55318
Submission Date:	May 26, 1998

2. Predicate Device

Lyphochek® Immunoassay Control Serum
Bio-Rad Laboratories
3726 E. Miraloma Avenue
Anaheim, CA 92806

510(k) Number: K891475

3. Device Description

The Access AFP QC are tri-level controls consisting of human AFP in human serum with preservatives. They are targeted to cover the assay range of approximately 7.0 ng/ml to 1725 ng/ml, with the controls targeted at 7, 80 and 1725 ng/ml.

4. Indications for Use

The Access AFP QC are controls intended for use in monitoring system performance of immunoenzymatic procedures for the quantitative measurement of alpha-fetoprotein (AFP) using the Access Immunoassay System.

5. Comparison of Technological Characteristics

The Access AFP QC and the Lyphochek Immunoassay Controls are both tri-level, human serum-based immunoassay controls intended to monitor the system performance of immunoassays for the measurement of AFP in human serum.

The Access AFP QC, intended for use with the Access AFP Reagents on the Access Immunoassay System are provided ready to use with an approximate range of 7.0 to 1725 ng/ml. The Lyphochek Immunoassay Controls, not designed for a specific immunoassay system, have approximate range of 30 to 280 ng/ml, depending on the assay used and require reconstitution.

6. Summary of Studies

Within-run, between-run and total imprecision of all three levels of the Access AFP QC were less than 5% CV. Access AFP QC are stable for up to 13 months when stored at 2-8° C

7. Conclusion

The Access AFP QC tri-level control materials are substantially equivalent to the Lyphochek Immunoassay Controls for the determination of system performance of AFP immunoassays based on similar features and reproducible results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 12 1998

Ellen M. Voss, M.S.
Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, Minnesota 55318-1084

Re: K981864
ACCESS® AFP QC on the ACCESS® Immunoassay Analyzer
Regulatory Class: I
Product Code: JJX
Dated: May 26, 1998
Received: May 27, 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 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/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 QC

Indications For Use:

The ACCESS® AFP QC (serum based) are tri-level controls intended for use in monitoring system performance of immunoenzymatic procedures for the quantitative measurement of alpha-fetoprotein (AFP) using the ACCESS Immunoassay System.

(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)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number k981864