DEC 2 0 2002

510(k) Summary

[As required by 21 CFR 807.92]

510(k) Number K023480 **Date Prepared:** 10/16/2002

Submitter	*Contact Person*
Beckman Coulter, Inc - Diagnostics Division 1000 Lake Hazeltine Drive Chaska, MN 55318	Denise Thompson Regulatory Affairs Specialist Phone: 952-368-1202; Fax: 952-368-7610

General Information

Trade Name	Access® Total βhCG
Common Name	Human chorionic gonadotropin
Classification Name	Human chorionic gonadotropin (HCG) test system (21 CFR 862.1155)

Device Description

The Access® Total βhCG assay consists of the reagent pack and calibrators. Consumables required for the assay include substrate and wash buffer.

Intended Use

The Access® Total βhCG assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total βhCG levels in human serum and plasma using the Access Immunoassay Systems.

Substantial Equivalence Comparison

The Access Total βhCG assay is substantially equivalent to the previously cleared Access Total βhCG assay (K980173). Both assays utilize the same methodology, are the same product type, and are quantitative. The subject and predicate assays include the same components. The only difference between the two assays is that the sample type has been expanded to include human plasma samples.

Supporting Data

To demonstrate substantial equivalence, a method correlation study, using paired plasma and serum samples, was conducted using the Access Total βhCG assay. Study results demonstrate good correlation between the plasma and serum samples.

Conclusion

The information provided in this submission supports a substantial equivalence determination, and therefore 510(k) premarket notification clearance of the Access Total βhCG assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 2 0 2002

Ms. Denise Thompson
Regulatory Affairs Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Re: k023480
Trade/Device Name: Access® Total βhCG on the Access® Immunoassay Systems
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI; JIT
Dated: October 16, 2002
Received: October 17, 2002

Dear Ms. Thompson:

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). Other general information on your responsibilities under the Act may be obtained 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

Indications Statement

510(k) Number: K023480

Device Name: **Access® Total βhCG on the Access® Immunoassay Systems**

Indications:

The Access Total βhCG assay provides *in vitro* quantitative determination of total βhCG levels in human serum and plasma. The Access Total βhCG assay is indicated for use with patients where an early detection of pregnancy status is desired.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓

prescription use

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023480