AUG 1 9 2005

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K052082

Submitter's Name and Address

Beckman Coulter, Inc.
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Chaska, MN 55318
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Contact: Carolyn Anderson

Date Prepared: August 1, 2005

Device Names

Proprietary Name: Ferritin on the Access® Immunoassay Systems

Common Name: Ferritin test system

Classification Name: Enzyme Immunoassay, Ferritin

Predicate Device

Access Ferritin Assay
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

510(k) Number: K926221

Device Description

The Access Ferritin reagents, Access Ferritin Calibrators and the Access Immunoassay Analyzers (Access, Access 2, Synchron LX®i 725, and UniCel DxI™ 800) comprise the Access Immunoassay Systems for the quantitative determination of ferritin levels in human serum and plasma (heparin).

Intended Use

The Access Ferritin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems.

Comparison of Technological Characteristics

Attribute	Access Ferritin Assay	Access Ferritin Assay (modified)
Methodology	Two site immunoenzymatic (sandwich) assay	Two site immunoenzymatic (sandwich) assay
Intended Use	Quantitative determination of ferritin levels in human serum and plasma (heparin)	Quantitative determination of ferritin levels in human serum and plasma (heparin)
Solid Phase	Paramagnetic particles coated with goat anti-mouse IgG	Paramagnetic particles coated with goat anti-mouse IgG
Conjugate	Goat anti-ferritin-alkaline conjugate	Goat anti-ferritin-alkaline conjugate
Calibrators	Human liver ferritin at levels of 0 and approximately 10, 50, 200, 500, and 1500 ng/mL (µg/L)	Human liver ferritin at levels of 0 and approximately 10, 50, 200, 500, and 1500 ng/mL (µg/L)

Summary of Technological Characteristics

The device modification consists of the addition of an auto-dilution feature that allows a 1:10 on-board system dilution of human serum and plasma (heparin) samples. The auto-dilution feature is intended for all Access Immunoassay Analyzers (Access, Access 2, SYNCHRON® LXi 725, and UniCel® DxI 800) and requires a change to the assay-specific software, referred to as the assay protocol file, for each member of this instrument family. The change does not affect assay performance characteristics.

A modification to the assay protocol file (APF) to ensure the main pipettor drops to a sufficient depth in the reagent pack when transferring material from the particle well and the conjugate well is being made to improve particle mixing and to ensure sufficient aspiration of reagents for transfer to the reaction vessel. This modification is being made for both the Ferritin and the auto-dilution (Dil-Ferritin) assays.

The Access Wash Buffer is currently used as the system buffer in the Access Ferritin assay on all Access Immunoassay Analyzers. The labeling is affected in that the directional insert has been revised to describe the addition of the auto-dilution feature. No changes have been made to the Access, Access 2, SYNCHRON® LXi 725, or UniCel® DxI 800 system software or hardware. The changes do not affect assay reaction kinetics. No changes have been made to the Access Ferritin assay reagents, calibrators or sample diluent. Access Wash Buffer is used to perform the auto-dilution.

Conclusion

The modified Access Ferritin on the Access Immunoassay Systems including on-board auto-dilutions is substantially equivalent to the Access Ferritin assay for the quantitative determination of ferritin levels in human serum and plasma (heparin).

I. continued...

C. Indications for Use Statement

The indications for use statement appears on the following page.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Beckman Coulter, Inc.
c/o Ms Carolyn Anderson
Sr. Regulatory Affairs Specialist
1000 Lake Hazeltine Dr.
Chaska, MN 55318-1084

AUG 1 9 2005

Re: k052082
Trade/Device Name: Ferritin on the Access® Immunoassay Systems
Regulation Number: 21 CFR 866.5340
Regulation Name: Ferritin immunological test system
Regulatory Class: Class II
Product Code: JMG
Dated: August 1, 2005
Received: August 2, 2005

Dear Ms. Anderson:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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 (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html

Sincerely yours,

Robert L. Becker, Jr., MD, Ph.D
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K052082

Device Name: Access Ferritin on the Access® Immunoassay Systems

Indications For Use:

The Access Ferritin assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of ferritin levels in human serum and plasma (heparin) using the Access Immunoassay Systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

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Office of In Vitro Diagnostic Device
Evaluation and Safety

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