FEB - 9 2005

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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: K050202

Submitter's Name and Address

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318
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Contact: Brent Taber

Date Prepared: January 27, 2005

Device Names

Proprietary Name: Cortisol and Cortisol Calibrators on the Access® Immunoassay Systems

Common Name: Cortisol (hydrocortisone and hydroxycorticosterone) test system

Classification Name: Radioimmunoassay, Cortisol

Predicate Device

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

510(k) Number: k954733

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Device Description

The Access Cortiosol reagents, Access Cortisol Calibrators and the Access Immunoassay Analyzers (Access, Access 2, Synchron LXi 725, and UniCel DxI 800) comprise the Access Immunoassay Systems for the quantitative determination of cortisol levels in human serum, plasma (heparin, EDTA) and urine.

Intended Use

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

Comparison of Technological Characteristics

Attribute	Access Cortisol Assay	Cortisol and Cortisol Calibrators on the Access Immunoassay Systems
Methodology	Competitive binding immunoenzymatic assay	Competitive binding immunoenzymatic assay
Intended Use	Quantitative determination of cortisol levels in human serum, plasma (heparin, EDTA) and urine	Quantitative determination of cortisol levels in human serum, plasma (heparin, EDTA) and urine
Solid Phase	Paramagnetic particles coated with goat anti-rabbit IgG	Paramagnetic particles coated with goat anti-rabbit IgG
Conjugate	Cortisol-alkaline phosphatase (bovine) conjugate	Cortisol-alkaline phosphatase (bovine) conjugate
Calibrators	Human serum containing cortisol (purified chemical compound) at levels of 0 and approximately 2, 5, 10, 25, and 60 µg/dL	Human serum containing cortisol (purified chemical compound) at levels of 0 and approximately 2, 5, 10, 25, and 60 µg/dL

Summary of Technological Characteristics

The device modification consists of a change to the directional insert. Cross-reactivity of the assay with substances that are similar in structure to cortisol was revised in the 'Analytical Specificity / Interferences' section. Urine cortisol concentration in 24-hour urine samples determined by extracted and unextracted methods was revised in the 'Expected Values' section.

Conclusion

Cortisol and Cortiosl Calibrators on the Access Immunoassay Systems is substantially equivalent to the Access Cortisol assay for the quantitative determination of cortisol levels in human serum, plasma (heparin, EDTA) and urine.

I. continued...

C. Indications for Use Statement

The indications for use statement appears on the following page.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 9 2005

Mr. Brent Taber
Staff Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

Re: k050202
Trade/Device Name: Cortisol and Cortisol Calibrators on the Access® Immunoassay Systems
Regulation Number: 21 CFR 862.1205
Regulation Name: Cortisol (hydrocortisone and hydroxycorticosterone) test system
Regulatory Class: Class II
Product Code: CGR, JIS
Dated: January 27, 2005
Received: January 28, 2005

Dear Mr. Taber:

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 (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,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k050202

Device Name: Cortisol and Cortisol Calibrators on the Access® Immunoassay Systems

Indications For Use:

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

A cortisol (hydrocortisone and hydroxycorticosterone) test system is a device intended to measure the cortisol hormones secreted by the adrenal gland in serum, plasma and urine. Measurements of cortisol are used in the diagnosis and treatment of disorders of the adrenal gland.

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 Device Evaluation (ODE)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K050202