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: K061282

Submitter's Name and Address

JUN - 2 2006

Beckman Coulter, Inc.
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Chaska, MN 55318
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Contact: Jennifer Ruether

Date Prepared: May 5, 2006

Device Names

Proprietary Name: Ultrasensitive hGH Calibrators on the Access® Immunoassay Systems

Common Name: Calibrators

Classification Name: Calibrator, Secondary (862.1150, JIT)

Predicate Device

Access Ultrasensitive hGH Calibrators
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

510(k) Number: K003089

Device Description

The Access Ultrasensitive hGH calibrators are lyophilized calibrators to be used with the Access Ultrasensitive hGH assay to generate the hGH calibration curve on the Access Immunoassay Systems. The Access Ultrasensitive hGH calibrator kit contains six 2.0 mL vials, one for each calibrator level. The Access Immunoassay Systems utilize a one-step immunoenzymatic ("sandwich") assay for the quantitative measurement of hGH.

Intended Use

The Access Ultrasensitive hGH Calibrators are intended to calibrate the Access Ultrasensitive hGH Assay for the quantitative determination of hGH levels in human serum and plasma using the Access Immunoassay Systems.

Summary of Technological Characteristics

Attribute	Access Ultrasensitive hGH Calibrators	Access Ultrasensitive hGH Calibrators (modified)
Intended Use	Calibration for quantitative determination of hGH levels in human serum and plasma	Calibration for quantitative determination of hGH levels in human serum and plasma
Calibrators	hGH at approximate levels of 0.1, 1.0, 10, 20, and 50 ng/mL (µg/L), lyophilized	hGH at approximate levels of 0.07, 0.7, 7, 14, or 35 ng/mL (µg/L), lyophilized
Traceability	Traceable to WHO 80/505	Traceable to WHO 98/574

The device modification consists of restandardizing the Access Ultrasensitive hGH Calibrators from the WHO Pituitary hGH 80/505 standard to the second international standard, WHO 98/574. The restandardization involves the use of the new WHO standard as the reference for assigning the calibrator values; there is no change to calibrator materials, functionality, or stability.

Conclusion

The restandardization of the Access Ultrasensitive hGH calibrators does not change the intended use or indications for use, alter the fundamental scientific technology, or affect the safety and efficacy of the device. Performance data generated from validation testing demonstrates that the restandardized Access Ultrasensitive hGH Calibrators on the Access Immunoassay Systems is substantially equivalent to the currently commercialized Access Ultrasensitive hGH calibrators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Jennifer Ruether
Regulatory Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

JUN - 2 2006

Re: k061282
Trade/Device Name: Access Ultrasensitive hGH Calibrators on the Access® Immunoassay Systems
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: May 5, 2006
Received: May 8, 2006

Dear Ms. Ruether:

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,

Alberto Gutierrez, Ph.D.
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 Statement

510(k) Number (if known): K061282

Device Name: Access Ultrasensitive hGH Calibrators on the Access® Immunoassay Systems

Indications For Use:

The Access Ultrasensitive hGH Calibrators are intended to calibrate the Access Ultrasensitive hGH Assay for the quantitative determination of hGH levels in human serum and plasma on 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)

Carol C Benson
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(Optional) K061282