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: k061190

Submitter's Name and Address

Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318
Telephone: (952) 368-1383
Fax: (952) 368-7610
Contact: Valynda Machen

SEP 15 2006

Date Prepared: August 15, 2006

Device Names

Proprietary Name:	Intact PTH and Intact PTH Calibrators on the Access® Immunoassay Systems
Common Name:	Parathyroid Hormone Test
Classification Name:	Radioimmunoassay, Parathyroid Hormone

Predicate Device(s)

Elecsys Parathyroid Hormone Test System
Roche Diagnostics Corporation
9115 Hague Rd
Indianapolis, IN 46250

510(k) Number: k992680

Immulite®/Immulite® 1000 Turbo Intact PTH
Diagnostic Products Corporation
Corporate Offices
5210 Pacific Concourse Drive
Los Angeles, CA 90045-6900

510(k) Number: k053533

Device Description

The Access Intact PTH reagents, calibrators, and the Access Immunoassay Analyzers (Access, Access 2, Synchron LXi 725, UniCel DxC600i, and UniCel DxI 800) comprise the Access Immunoassay Systems for the determination of intact parathyroid hormone (PTH) levels in human serum and plasma.

Intended Use

The Access Intact PTH assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of intact parathyroid hormone (parathyrin, PTH) levels in human serum and plasma using the Access Immunoassay Systems. It is indicated to aid in the differential diagnosis of hyperparathyroidism, hypoparathyroidism, or hypercalcemia of malignancy and can be used intraoperatively. Assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decisions.

Comparison of Technological Characteristics

Attribute	Roche Elecsys Parathyroid Hormone Test System	Immulite/Immulite 1000 Turbo Intact PTH	Access Intact PTH
Intended Use	Immunoassay for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia.	For in vitro diagnostic use with the IMMULITE and IMMULITE 1000 Analyzers-for the quantitative measurement of intact parathyroid hormone (parathyrin, PTH) in EDTA plasma or serum. It is intended as an aid in the differential diagnosis of hypercalcemia and hypocalcemia and can be used intraoperatively.	The Access Intact PTH assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of intact parathyroid hormone (parathyrin, PTH) levels in human serum and plasma using the Access Immunoassay Systems. It is indicated to aid in the differential diagnosis of hyperparathyroidism, hypoparathyroidism, or hypercalcemia of malignancy and can be used intraoperatively.
Assay Principles	Electrochemiluminescence immunoassay employing the sandwich principle.	Solid phase, chemiluminescent immunometric assay.	The Access Intact PTH assay is a two-site immunoenzymatic ("sandwich") assay.
Solid Support	Streptavidin coated microparticles.	Bead coated with affinity purified goat polyclonal anti-PTH (44-84) antibody.	Paramagnetic particles coated with goat anti-PTH.
Detection System	Chemiluminescent emission.	Chemiluminescent emission.	Utilizes dioxetane-based chemiluminescent substrate; Measures light production from a chemiluminescent reaction.
Calibrator	2 point calibration and master curve provided via the reagent barcode.	Intact PTH Adjustors (Low and High) of lyophilized synthetic human intact PTH in a buffered matrix.	Six levels (0, ~10, ~60, ~300, ~1500, and ~3500 pg/mL) of synthetic PTH antigen in a buffered protein solution with preservatives.

Summary of Analytical Studies

Imprecision: Imprecision was tested for concentrations from approximately 12 to 1400 pg/mL. Total imprecision ranged from 2.8% to 6.4% CV for the routine mode and 3.1% to 10.6% CV for the intraoperative mode.

Dilution Recovery (Linearity): Multiple dilutions of EDTA plasma samples were analyzed in the routine mode and intraoperative modes. Mean % recovery ranged from 91% to 103% for the routine mode and 85% to 98% for the intraoperative mode.

Methods Comparison:
A comparison of 500 values using the Access Intact PTH assay routine mode and a commercially available immunoassay system gave the following statistical data using Deming calculations: Range of observations=16-2627 pg/mL, Intercept=-11.5 pg/mL, Slope=1.09, Correlation coefficient (r)=0.99.

A comparison of 493 values using the Access Intact PTH assay routine mode and the intraoperative mode on the Access Immunoassay system gave the following statistical data using Deming calculations: Range of observations=13-2848 pg/mL, Intercept=9.69 pg/mL, Slope=0.94, Correlation coefficient (r)=1.00.

A comparison of 393 values using the Access Intact PTH intraoperative mode and a commercially available immunoassay system gave the following statistical data using Deming calculations: Range of observations=8-2453 pg/mL, Intercept=0.13 pg/mL, Slope=0.87, Correlation coefficient (r)=1.00.

Analytical Specificity: There was no significant interference from potential sample contaminants (bilirubin, hemoglobin, human serum albumin, and triglycerides) in either the routine or intraoperative modes.

Stability: Intact PTH reagents are stable for 28 days after opening. Intact PTH calibrators are singe use only. The calibration is stable for 28 days.

Summary of Clinical Studies

To establish a reference range, PTH concentrations were measured in 289 matched human EDTA plasma and serum samples from apparently healthy male and female subjects aged 19-67 years. Because of significant seasonal variations of 25-hydroxyvitamin D, the samples were collected during three time periods in two geographic latitudes. Additional testing was performed to exclude individuals with abnormal serum calcium, creatinine or 25-hydroxyvitamin D. A 95% non-parametric reference interval of 12-88 pg/mL was determined. Routine and intraoperative mode reference intervals are equivalent.

Conclusion

Intact PTH and Intact PTH Calibrators on the Access Immunoassay Systems is substantially equivalent to the Roche Elecsys Parathyroid Hormone Test System and the Immulite/Immulite 1000 Turbo Intact PTH assay for the quantitative determination of intact PTH levels in human serum and plasma.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Valynda Machen
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318

SEP 15 2006

Re: k061190
Trade/Device Name: Access Intact PTH Assay
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW, JIT
Dated: August 14, 2006
Received: August 16, 2006

Dear Ms. Machen:

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

510(k) Number (if known): k061190

Device Name: Access Intact PTH Assay

Indications For Use:

The Access Intact PTH assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of intact parathyroid hormone (parathyrin, PTH) levels in human serum and plasma using the Access Immunoassay Systems. It is indicated to aid in the differential diagnosis of hyperparathyroidism, hypoparathyroidism, or hypercalcemia of malignancy and can be used intraoperatively. Assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decisions.

The Access Intact PTH Calibrators are intended to calibrate the Access Intact PTH assay for the quantitative determination of intact parathyroid hormone (parathyrin, PTH) levels in human serum and plasma using the Access Immunoassay Systems.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ (21 CFR 807 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

510(k) K061190