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K023764

9 510(K) SUMMARY

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.

510(k) Number _____ **Date Prepared:** November 8, 2002

Submitter	*Contact Person*
Beckman Coulter, Inc Diagnostics Division 1000 Lake Hazeltine Drive Chaska, MN 55318	Lynn S. Weist Staff Regulatory Affairs Specialist Phone: 952-368-1271 Fax: 952-368-7610

General Information

Trade Name	UniCel™ Dxl 800 Access® Immunoassay System
Common Name	Discrete photometric chemistry analyzer for clinical use
Classification Name	Discrete photometric chemistry analyzer for clinical use
Legally Marketed (Predicate) Device	Access® 2 Immunoassay System, Manufactured by Beckman Coulter, Inc., (K922823 "Add to File" Letter, dated May 18, 2001 and PMA Supplement P980041/S001, cleared October 1, 2002)

Device Description

The UniCel Dxl 800 Access Immunoassay System is a floor model, microcomputer controlled, random and continuous access analyzer that performs enzyme immunoassays (EIA) utilizing a paramagnetic particle solid phase and chemiluminescent detection.

Intended Use

The UniCel Dxl 800 Access Immunoassay System is an in vitro diagnostic device used for the quantitative, semi-quantitative or qualitative determination of various analyte concentrations found in human body fluids.

Substantial Equivalence Comparison

The UniCel Dxl 800 system represents an evolutionary change to the Access 2 Immunoassay System design. The modifications to the basic Access 2 platform support at least three major improvements desirable to the customer with medium-high testing volume. These are: 1) increased throughput,

2) on-board process monitoring and 3) release of the primary sample tubes back to the laboratory workflow as early as possible.

The main modifications to the design include an obstruction detection feature, larger volume bulk supplies to accommodate higher throughput, the method of vessel handling, incorporation of sensors and encoders at key points for process monitoring and the addition of a sample pipettor and refrigerated on-board sample aliquot storage.

Reagent pipetting, fluid handling, reagent chemistry, assay incubation temperature and timing, signal detection and assay data processing are all unchanged from the Access 2 design. The DxI uses the same Access Immunoassay System assays and calibrators, packaged the same as for Access 2. The formulations of the substrate and wash buffer used with the Access assays are unchanged. There are no changes to the intended uses, technical specifications or final performance specifications and claims for the assays.

Supporting Data

In order to demonstrate that the DxI system is substantially equivalent to the Access 2, method comparison, precision and analytical sensitivity studies were conducted using five representative assays. Method correlation studies demonstrated good correlation between the Access 2 and DxI systems on each of the five assays. Each of the five assays met its established acceptance criteria for precision and analytical sensitivity.

Conclusion

The information provided in this submission supports a substantial equivalence determination, and therefore 510(k) premarket notification clearance of the UniCel DxI 800 Access Immunoassay System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Lynn S. Weist
Staff Regulatory Affairs Specialist
Beckman Coulter, Inc.
1000 Lake Hazeltine Drive
Chaska, MN 55318-1084

JAN 28 2003

Re: k023764
Trade/Device Name: UniCel™ Dxl 800 Access® Immunoassay System
Regulation Number: 21 CFR 862.1215
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system
Regulatory Class: Class II
Product Code: MMI, JJE, CEC, CGR, CHP, JLW
Dated: November 8, 2002
Received: November 12, 2002

Dear Ms. Weist:

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

ATTACHMENT B: INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023764

PAGE 1 OF 1

Device Name: UniCel™ Dxl 800 Access® Immunoassay System

Indications for Use:

The UniCel Dxl 800 Access Immunoassay System is a microcomputer controlled, random and continuous access analyzer that includes an external computer. This computer stores the system user interface (UI) software and allows the operator to interface with and direct the instrument software. The UniCel Dxl 800 System uses enzyme immunoassays (utilizing paramagnetic particle solid phase and chemiluminescent detection) for the quantitative, semi-quantitative or qualitative determination of various analyte concentrations found in human body fluids. The UniCel Dxl 800 System is an in vitro diagnostic device for use in the clinical laboratory.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Veronica J Calvin for Dr Jean Cooper (Optional Format 3-10-98)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023764

INDICATIONS FOR USE STATEMENT Page 1 of 1

510(k) Number (if known): _____

Device Name: AccuTnI™ and AccuTnI Calibrators on the Access® Immunoassay Systems

Indications For Use:

The Access AccuTnI assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of cardiac troponin I (cTnI) levels in human serum and plasma using the Access Immunoassay Systems to aid in the diagnosis and treatment of myocardial infarction and cardiac muscle damage.

Cardiac troponin I determination aids in the risk stratification of patients with unstable angina or non-ST segment elevation acute coronary syndromes with respect to relative risk of mortality, myocardial infarction, or increased probability of ischemic events requiring urgent revascularization procedures.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

W. Celnik for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023764

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

INDICATIONS FOR USE STATEMENT Page 1 of 1

510(k) Number (if known): _____

Device Name: Access® Cortisol 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.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

D Celwin for Jean Cooper

(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number K023764

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

INDICATIONS FOR USE STATEMENT Page 1 of 1

510(k) Number (if known): _____

Device Name: Access® Estradiol on the Access® Immunoassay Systems

Indications For Use:

The Access Estradiol assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of Estradiol levels in human serum, using the Access Immunoassay Systems.

Levels of estradiol are useful in monitoring ovulatory status. Because Estradiol levels reflect follicular maturation, the measurement of estradiol is a valuable tool in the assessment of sexual development, etiology of amenorrhea, causes of infertility and menopause. Abnormally high levels in males are indicative of feminizing syndromes such as gynecomastia.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

D Calvin for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023764

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

INDICATIONS FOR USE STATEMENT Page 1 of 1

510(k) Number (if known): _____

Device Name: Access® Free T4 on the Access® Immunoassay Systems

Indications For Use:

The Access Free T4 assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of free thyroxine levels in human serum and plasma (heparin) using the Access Immunoassay Systems.

A free thyroxine test system is a device intended to measure free (not protein bound) thyroxine (thyroid hormone) in human serum or plasma (heparin). Levels of free thyroxine in plasma are thought to reflect the amount of thyroxine hormone available to the cells and may therefore determine the clinical metabolic status of thyroxine. Measurements obtained by this device are used in the diagnosis and treatment of thyroid diseases.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

D Celwin for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023764

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

INDICATIONS FOR USE STATEMENT Page 1 of 1

510(k) Number (if known): _____

Device Name: Access® HYPERsensitive hTSH on the Access® Immunoassay Systems

Indications For Use:

The Access HYPERsensitive hTSH assay provides in vitro quantitative measurement of human thyroid stimulating hormone (hTSH) in human serum or plasma. The Access HYPERsensitive hTSH assay is indicated for use with patients where an evaluation of their thyroid status is desired.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

V. Calvin for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023764

Prescription Use ✓ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)