K071039

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4. 510(k) Summary

Owner's Name & Address:
Diamond Diagnostics Inc
333 Fiske Street
Holliston MA 01746
FAX: 508-429-0452

Contact Person:
Kathryn Thorsen
Quality Assurance Manager
508-429-0450 x357

Establishment Registration Number: 3003030793

AUG - 8 2007

Date of Preparation: April 10, 2007

Identification of the Device:

Proprietary/Trade name: Mission Olympus AU ISE Calibrators
Common name Calibrating Standard
Classification name: Calibrator, Secondary (21 CFR 862.1150, Product Code JIT). The product code of JIT has been assigned to this device in the Classification Database.

Substantial Equivalence Table of Product Part Numbers & Trade Names

Diamond/Mission Product	Olympus Equivalent
OY-AUH1012D ISE Mid Standard	AUH1012 ISE Mid Standard
OY-AUH1014D ISE Low Standard	AUH1014 ISE Low Standard
OY-AUH1015D ISE High Standard	AUH1015 ISE High Standard
OY-AUH1016D Low/High Urine Standard	AUH1016 Low/High Urine Standard

Description of Device:
Mission Olympus AU ISE Calibrators are intended to serve as a direct replacement to Olympus AU ISE Calibrators.

Intended Use:
Mission Olympus AU ISE Calibrators are intended to provide calibration points for Na+, K+ and Cl- electrodes on the Olympus AU4xx and AU6xx instruments.

Technological Characteristics:

Characteristics	Mission Olympus AU ISE Calibrators	Olympus AU ISE Calibrators
PN	OY-AUH1012D, OY-AUH1014D, OY-AUH1015D, OY-AUH1016D	AUH1012, AUH1014, AUH1015, AUH1016
Contents:	Aqueous solution of salts & preservatives Contains NO human or animal materials.	Aqueous solution of salts & preservatives Contains NO human or animal materials.
Container	Plastic bottles	Plastic bottles
Color	Clear solution	Clear solution
Package	OY-AUH1012D: 4 x 2L bottles in corrugated box, OY-AUH1014D & OY-AUH1015D: 4 X 100mL bottles with dropper tips & caps in corrugated box, OY-AUH1016D: 2 x 100mL Low Urine Standard (OY-AUH1016AD) & 2 x 100mL High Urine Standard (OY-AUH1016BD) all in plastics bottles with dropper tips & caps in corrugated box	AUH1012: 4 x 2L bottles in corrugated box, AUH1014 & AUH1015: 4 X 100mL bottles with dropper tips & caps in corrugated box, AUH1016: 2 x 100mL Low Urine Standard & 2 x 100mL High Urine Standard all in plastics bottles with dropper tips & caps in corrugated box
Intended Use	For in-vitro diagnostics use to provide calibration points for Na+, K+ and Cl- electrodes on the Olympus AU4xx and AU6xx instruments.	For in-vitro diagnostics use to provide calibration points for Na+, K+ and Cl- electrodes on the Olympus AU4xx and AU6xx instruments.
Storage / Shelf Life	18-25°C 24-months	18-25°C 24-months

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Assessment of Non-Clinical Performance Data:

Tests were conducted to verify specific performance requirements:

a. Accelerated (high temperature) stress test to support stability
b. Side by side testing of Mission Olympus AU ISE Calibrators vs. Predicate (OEM) product on intended instruments to demonstrate equivalence

Assessment of Clinical Performance Data:

NA

Conclusions:

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Diamond Diagnostics Inc.
c/o Ms. Kathryn Thorsen
Quality Assurance Manager
333 Fiske Street
Holliston, MA 01746

AUG - 8 2007

Re: k071039
Trade/Device Name: Mission Olympus AU ISE Calibrators
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: June 22, 2007
Received: June 25, 2007

Dear Ms. Thorsen:

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) 276-0490. 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 (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., 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

4. Indications for Use Statement

510(k) Number (if known): K071039

Device Name: Mission Olympus AU ISE Calibrators

Indications For Use:

Mission Olympus AU ISE Calibrators are intended to provide calibration points for Na+, K+ and Cl- electrodes on the Olympus AU400 and AU600 instruments.

For *In Vitro* Diagnostic Use

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

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K071039