K093357

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92

Applicant: Diamond Diagnostics Inc
333 Fiske Street
Holliston MA 01746

Contact Person: Kathy Cruz
Quality Assurance Manager
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JUN 24 2010

Date Prepared: October 27, 2009

Controls:

Classification Name: Calibrator, secondary
Trade Name: Calibrating Material, Calibrating Standards
Device Classification: 21 CFR 862.1150
Device Class: Class II
Classification Panel: Clinical Chemistry
Product Code: JIT

Intended Use:

Diamond Calibrators for Medica ISE Module are intended for *in-vitro* diagnostics use to provide calibration points for the Na^+, K^+, and Cl^- electrodes on the Polymedco Poly-Chem and Randox Daytona instruments having the Medica ISE Module.

Description of Device:

Diamond Calibrant A matrix consists of a buffered solution of electrolytes and preservative. It contains no human or biological materials. It is packaged in a foil bag with a draw tube and covered in a corrugated box. Each foil bag contains 500 ml of solution.

Diamond Calibrant B matrix consists of a buffered solution of electrolytes and preservative. It contains no human or biological materials. It is packaged in a plastic bottle with a cap. Each plastic bottle contains 125 ml of solution.

PN	ISE Module Calibrator	Na^+ mmol/L	K^+ mmol/L	Cl^- mmol/L
ME-6370D	A	140 ± 2.0	4.00 ± 0.05	125 ± 2
ME-5410D	B	70 ± 1.5	8.0 ± 0.08	41 ± 1.5

Predicate Device: Medica ISE Module Calibrators

Predicate 510(k) number(s): K070057

Comparison with predicate:

Characteristics	Diamond Calibrators for Medica ISE Module	Medica ISE Module Calibrators
PN	ME-6370D, ME-5410D	006370-001, 5410
Product Type	Calibrator	Calibrator
Intended Use	For *in-vitro* diagnostics use to provide calibration points for the Na^+, K^+, and Cl^- electrodes on the Polymedco Poly-Chem, and Randox Daytona instruments having the Medica ISE Module	For *in-vitro* diagnostics use to provide calibration points for the Na^+, K^+, and Cl^- electrodes on the Polymedco Poly-Chem, Randox Daytona, and Medica Easy Electrolytes instruments having the Medica ISE Module
Matrix	Buffered solution of salts & preservatives Contains NO human or animal materials.	Buffered solution of salts & preservatives Contains NO human or animal materials.
Packaging	Plastic bottle, Foil Bag	Plastic bottle, Foil Bag
Color	Clear solution	Clear solution
Storage	18-25°C	18-25°C
Shelf Life for ME-6370D	30 months	36 Months
Shelf Life for ME-5410D	28 months	36 Months

Executive Summary

Based on the results submitted in this pre market notification Diamond Medica ISE Module Calibrators claim substantial equivalence to the Medica ISE Module Calibrators in Composition, which is, Na^+, K^+, and Cl^-, Intended use, Packaging, and Storage.

Diamond Calibrators for Medica ISE Module were tested side by side with the predicate device on the Poly-Chem (Polymedco) Analyzer and Randox Daytona instruments. The Medica ISE Module is a component of this Analyzer. Results show equivalent performance for Na^+, K^+, and Cl^- calibration and precision. The devices show good correlation.

Substantial Equivalence Discussion

Diamond Diagnostics claims substantial equivalence to the predicate calibrators listed below:

Substantial Equivalence Table of Product PN's & Trade Names

Diamond Diagnostics Product		Medica ISE Module Calibrators	
ME-6370D	Diamond Medica ISE Module Calibrant A	006370-001	Medica ISE Module Calibrant A
ME-5410D	Diamond Medica ISE Module Calibrant B	5410	Medica ISE Module Calibrant B

Diamond Diagnostics claims substantial equivalence to the Medica ISE Module Calibrators for Composition, Intended use, Packaging, and Storage.

The table below compares Diamond Diagnostics Calibrators to the Predicate.

Comparison Tables of Characteristics – Diamond vs Medica – by product

Characteristics	Diamond Medica ISE Module Calibrators	Medica ISE Module Calibrators
PN	ME-6370D, ME-5410D	006370-001, 5410
Product Type	Calibrator	Calibrator
Intended Use	For *in-vitro* diagnostics use to provide calibration points for the Na^+, K^+, and Cl^- electrodes on the Polymedco Poly-Chem, and Randox Daytona instruments having the Medica ISE Module	For *in-vitro* diagnostics use to provide calibration points for the Na^+, K^+, and Cl^- electrodes on the Polymedco Poly-Chem, Randox Daytona, and Medica Easy Electrolytes instruments having the Medica ISE Module
Matrix	Buffered solution of salts & preservatives Contains NO human or animal materials.	Buffered solution of salts & preservatives Contains NO human or animal materials.
Packaging	Plastic bottle, Foil Bag	Plastic bottle, Foil Bag
Color	Clear solution	Clear solution
Storage	18-25°C	18-25°C
Shelf Life for ME-6370D	30 months	36 months
Shelf Life for ME-5410D	28 months	36 months

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Diamond Diagnostics Inc.
c/o Kathy Cruz
333 Fiske Street
Holliston, Massachusetts 01746

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

JUN 24 2010

Re: k093357
Trade Name: Diamond Calibrators for Medica ISE Module
Regulation Number: 21 CFR§862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIT
Dated: June 17, 2010
Received: June 18, 2010

Dear Ms. Cruz:

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney C. Harper, 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): K093357

Device Name: Diamond Calibrators for Medica ISE Module

Indications for Use:

Diamond Calibrators for Medica ISE Modules are intended for *in-vitro* diagnostics use to provide calibration points for the Na^+, K^+, and Cl^- electrodes on the Polymedco Poly-Chem and Randox Daytona instruments having the Medica ISE Module.

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) K093357