MAR 1 0 2010

510(k) Summary

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

The Assigned 510(k) Number is: **k093384**

Applicant: Diamond Diagnostics, Inc.
333 Fiske Street
Holliston, MA 01746

Contact Person: Kathy Cruz
Qaulity Assurance Manager
Phone: (508) 429-0450 ext. 358
Fax: (508) 429-0452

Date Prepared: March 4, 2010

Controls:

Classification Name: Controls for blood-gases (Assayed and Un-Assayed)

Trade Name: Mission Trinity R

Device Classification: 21 CFR 862.1660

Device Class: Class I

Classification Panel: Clinical Chemistry

Product Code: JJY

Intended Use:

Mission Trinity R™ Control is intended to be used as an assayed quality control material for monitoring the precision and performance of the following analytes pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, and lactate on blood gas, electrolyte, and metabolite analyzers as well as tHb, $\%O_2Hb$, $\%O_2Sat$, %COHb, %MetHb, $\%O_2Ct$ & %HHb on **CO-Oximeter instrumentation.** It is for *in vitro* diagnostics use and for the quantitative determination of the analytes listed on the Expected Values Chart.

Device Description:

Trinity R matrix consists of a buffered solution of electrolytes, glucose, lactate, dyes and preservative. It is equilibrated with specific levels of CO_2, O_2, and N_2. It contains no human or biological materials. **Trinity R** is provided in three (3) distinct levels of pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate, tHb, $\%O_2Hb$, % HbO_2Sat, %COHb, %MetHb, $\%O_2Ct$ & %HHb covering the significant range of the instrument performance. It is packaged in sealed glass ampules, each containing 1.8 ml of solution. Ampules are packaged in single level boxes (30 ampules of same level) or tri-level boxes (10 ampules of each level).

Predicate Device name:

RNA Medical RA 525 Blood Gas, Electrolyte, Metabolite, CO-OXimeter (Radiometer) Control

Predicate 510(k) number(s):

K880447

Comparison with predicate:

Similarities

Characteristics	Mission Trinity R	RNA Medical RA 525 Blood Gas, Electrolyte, Metabolite, CO-OXimeter (Radiometer)
510(K) Number	K093384	K880447
Product Type	Assayed Blood Gas Control	Assayed Blood Gas Control
Intended Use	For *in vitro* diagnostics use for quality control of pH/Blood Gas analyzers, ISE analyzers, Metabolite analyzers and CO-OXimeter Instrumentation.	Same
Matrix	Buffered Aqueous Solution	Same
Storage	2-8°C	Same
Color	Red/purple solution	Same
Levels	Three	Same
Analytes	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate, tHb, %O2Hb, %COHb, %metHb, %02Ct, %O2Sat and %HHb	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate, tHb, %O2Hb, %COHb, %metHb, %02Ct, %O2Sat and %HHb

Differences

Characteristics	Mission Trinity R	RNA Medical RA 525 Blood Gas, Electrolyte, Metabolite, CO-OXimeter (Radiometer)
Preservative	Present	Not present
Package	30 X 1.8mL	30 X 2.5mL
Shelf Life	24 months	36 months

Substantial Equivalence Discussion

Mission claims substantial equivalence to RNA Medical RA525 Controls listed below:

Substantial Equivalence Table of Product PN's & Trade Names

Mission Product		RNA Medical RA 525	
DD-97001D	Mission Trinity R Control (Level 1)	RA 525-1	RNA Medical RA 525 Blood Gas, Electrolyte, Metabolite, CO-OXimeter (Radiometer) Control (Level 1)
DD-97002D	Mission Trinity R Control (Level 2)	RA 525-2	RNA Medical RA 525 Blood Gas, Electrolyte, Metabolite, CO-OXimeter (Radiometer) Control (Level 2)
DD-97003D	Mission Trinity R Control (Level 3)	RA 525-3	RNA Medical RA 525 Blood Gas, Electrolyte, Metabolite, CO-OXimeter (Radiometer) Control (Level 3)
DD-97123	Mission Trinity R Control (Multi-Level)	RA 525	RNA Medical RA 525 Blood Gas, Electrolyte, Metabolite, CO-OXimeter (Radiometer) Control (Multi-Level)

Mission claims substantial equivalence to RNA Medical RA525 for Composition, Intended use, Packaging, Storage, and Shelf life.

The tables below compare Mission to RNA Medical RA525.

Comparison Tables of Characteristics – Mission vs RNA Medical – by product

Characteristics	Mission Trinity R	RNA Medical RA 525 Blood Gas, Electrolyte, Metabolite, CO-OXimeter (Radiometer) k880447
Product Type	Assayed Blood Gas Control	Assayed Blood Gas Control
Intended Use	For *in vitro* diagnostics use for quality control of pH/Blood Gas analyzers, ISE analyzers, Metabolite analyzers and CO-OXimeter Instrumentation.	For *in vitro* diagnostics use for quality control of pH/Blood Gas analyzers, ISE analyzers, Metabolite analyzers and CO-OXimeter Instrumentation.
Matrix	Buffered Aqueous Solution	Buffered Aqueous Solution
Storage	2-8°C	2-8°C
Color	Red/purple solution	Red/purple solution
Levels	1, 2, 3	1, 2, 3
Analytes	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate, tHb, %O2Hb, %COHb, %metHb, %02Ct, %O2Sat and %HHb	pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, lactate, tHb, %O2Hb, %COHb, %metHb, %02Ct, %O2Sat and %HHb
Preservative	Present	Not present
Package	30 X 1.8mL	30 X 2.5mL
Shelf Life	24 months	36 months

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

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

MAR 10 2010

Re: k093384
Trade Name: Mission Trinity R Blood Gas Controls
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality Control Material Assayed and Unassayed.
Regulatory Class: Class I, reserved
Product Codes: JJY
Dated: January 4, 2010
Received: January 4, 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): K093384

Device Name: Mission Trinity R

Indications for Use:

Mission Trinity R™ Control is intended to be used as an assayed quality control material for monitoring the precision and performance of the following analytes pH, pCO_2, pO_2, Na^+, K^+, Ca^{++}, Cl^-, glucose, and lactate on blood gas, electrolyte, and metabolite analyzers as well as tHb, $\%O_2Hb$, $\%O_2Sat$, %COHb, %MetHb, $\%O_2Ct$ & %HHb on **CO-Oximeter instrumentation.**

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 OF 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) K093384