5. 510(k) Summary

510(k) Number: k124009

APR 17 2013

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

Contact Person: Kathy Cruz
Quality Assurance Manager
Phone: (508) 429-0450 ext. 351
Fax: (508) 429-0452

Date Prepared: April 17, 2013

Classification Name: Assayed Quality Control Material

Trade Name: Mission CliniCheck Assayed Chemistry Control

Device Classification: 21 CFR 862.1660

Device Class: Class I (Reserved)

Classification Panel: Clinical Chemistry

Product Code: JJY

Intended Use: Mission CliniCheck Controls is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the following analytes, Acetaminophen, Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Alpha-1 Anti-Trypsin, Alpha Fetoprotein, Alpha Hydroxybutyrate Dehydrogenase (α-HBDH), Amylase, Apolipoprotein A-1 (APO-A1), Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct), Bilirubin (Total), C3 Complement, C4 Complement, Calcium, Carbon Dioxide (CO_2), Carcinoembryonic Antigen (CEA), Ceruloplasmin, Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatine Kinase (CK), Creatinine, Digoxin, Gamma Glutamyltransferase (GGT), Glucose, Haptoglobin, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron, Iron-Binding Capacity, Total (TIBC), Iron Binding Capacity, Unsaturated (UIBC), Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Salicylate, Sodium, T3 Free, T3 Total, T4 Free, T4 Total, Thyroid Stimulating Hormone (TSH), Transferrin, Triglycerides, Urea, Urea Nitrogen, and Uric Acid on instruments listed in the expected values chart.

Device Description: Mission CliniCheck Assayed Chemistry Control is a human serum based product containing constituents of purified biochemicals (tissue extracts of human and animal origin), chemicals, therapeutic drugs, preservatives and stabilizers. Two levels of Control are provided in a lyophilized form. Each level is packaged into a glass amber bottle containing 5mL of product. The product is packaged in single level boxes (12 x 5mL) or multiple level boxes (6 x 2 x 5mL) and stored at 2 - 8°C.
All human source material was tested and found negative by FDA approved methods for HBsAg, HCV, and HIV-1/2.

Value Assignment: Mission CliniCheck Assayed Chemistry Control value assignment is lot specific. Lot to lot variation is determined by testing new lot vs. previous lot normalized to either a serum standard made with corresponding analyte NIST or Original Equipment Manufacturer (OEM). The target values are obtained by testing 16 replicates, 4 replicates each over a period of 4 days. The average of these 16 data points is the mean. The range is then determined by multiplying the mean by $\pm$ 20%, creating the upper and lower range. All testing is performed alongside (OEM) Original Equipment Manufacturer material to verify values before accepting new ranges.

Predicate Device: Mission CliniCheck Assayed Chemistry Control, Levels 1 and 2

Predicate 510(k): K103364

Comparison with Predicate Device:

Product	New Device	Predicate
Name	Mission CliniCheck Assayed Chemistry Control	Same
510(k)	K124009	k103364
PN	DD-93001D, DD-93002D	Same
Intended Use	For *in vitro* diagnostic use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the following analytes, Acetaminophen, Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Alpha-1 Anti-Trypsin, Alpha Fetoprotein, Alpha Hydroxybutyrate Dehydrogenase (α-HBDH), Amylase, Apolipoprotein A-1 (APO-A1), Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct), Bilirubin (Total), C3 Complement, C4 Complement, Calcium, Carbon Dioxide (CO_2), Carcinoembryonic Antigen (CEA), Ceruloplasmin, Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatine Kinase (CK), Creatinine, Digoxin, Gamma Glutamyltransferase (GGT), Glucose, Haptoglobin, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron, Iron-Binding Capacity, Total (TIBC), Iron Binding Capacity, Unsaturated (UIBC), Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Salicylate, Sodium, T3 Free, T3 Total, T4 Free, T4 Total, Thyroid Stimulating Hormone (TSH), Transferrin, Triglycerides, Urea, Urea Nitrogen, and Uric Acid on instruments listed in the expected values chart.	Not assayed for Acetaminophen, Alpha-1 Anti-Trypsin, Alpha Fetoprotein, Carcinoembryonic Antigen, Ceruloplasmin, Digoxin, Haptoglobin
Matrix	Serum	Same
Form	Lyophilized	Same
Levels	Two	Same
Storage	2-8°C	Same
Reconstituted Stability	20 days at -20°C	Same
Shelf Life	24 months	Same
Packaging	12 x 5 mL	Same

Stability

Tests were conducted to determine stability. Accelerated (high temperature) stress test was done and results support a 2 year shelf life when the controls are stored at 2-8°C. Testing showed that reconstituted Mission CliniCheck Assayed Chemistry Controls are stable for up to 20 days at -20°C. Once thawed, the controls cannot be refrozen and must be discarded. Values are also stable for 7 days when stored at 2-8°C with the following exception: Acid Phosphatase will be stable for 3 days, AST for 1 day, CK, LDH, T4 free and TSH for 6 days when stored tightly capped at 2-8°C.

Conclusion:

Based on the results submitted in this pre market notification Mission CliniCheck Assayed Chemistry Control claims substantial equivalence to the predicate device in Composition, that is Acetaminophen, Acid Phosphatase (Total), Alanine Aminotransferase (ALT/GPT), Albumin, Alkaline Phosphatase (ALP), Alpha-1 Anti-Trypsin, Alpha Fetoprotein, Alpha Hydroxybutyrate Dehydrogenase (α-HBDH), Amylase, Apolipoprotein A-1 (APO-A1), Aspartate Aminotransferase (AST/GOT), Bilirubin (Direct), Bilirubin (Total), C3 Complement, C4 Complement, Calcium, Carbon Dioxide (CO_2), Carcinoembryonic Antigen (CEA), Ceruloplasmin, Chloride, Cholesterol (Total), HDL-Cholesterol, LDL-Cholesterol, Cholinesterase, Creatine Kinase (CK), Creatinine, Digoxin, Gamma Glutamyltransferase (GGT), Glucose, Haptoglobin, Immunoglobulin A (IgA), Immunoglobulin G (IgG), Immunoglobulin M (IgM), Iron, Iron-Binding Capacity, Total (TIBC), Iron Binding Capacity, Unsaturated (UIBC), Lactate (Lactic acid), Lactate Dehydrogenase (LDH), Lipase, Lithium, Magnesium, Phosphorus, Potassium, Protein-Total, Salicylate, Sodium, T3 Free, T3 Total, T4 Free, T4 Total, Thyroid Stimulating Hormone (TSH), Transferrin, Triglycerides, Urea, Urea Nitrogen, and Uric Acid, Intended use, Packaging, Storage, and Shelf life

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 17, 2013

Diamond Diagnostics, Inc.
C/O Kathy Cruz
333 Fiske St
HOLLISTON MA 01746

Re: K124009
Trade/Device Name: Mission CliniCheck Assayed Chemistry Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: I, reserved
Product Code: JJY
Dated: March 20, 2013
Received: April 04, 2013

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for

the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -S for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k124009

Device Name: Mission CliniCheck Assayed Chemistry Control

Indications for Use:

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Prescription Use ___X___ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use _ (21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Yung W. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health

510(k)___k124009_____