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5. 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.

The Assigned 510(k) number is K103387.

Submitter's Identification:

ACON Laboratories, Inc.
10125 Mesa Rim Road
San Diego, California 92121

Tel.: 858-875-8019
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Date Prepared: November 2010

Contact Person:

Richard Lenart
Regulatory Affairs Manager

Proprietary Name of the Devices:

Mission® Liquid Urine Control, Mission® Liquid Diptube Urine Control, Mission® Dry Strip Urine Control

Common Name:

Urinalysis Controls

Regulation Section and Classification:

21 CFR § 862.1660 Quality control material (assayed and unassayed)

Class I (general controls)

Product Code:

JJW Urinalysis controls (assayed and unassayed)

Medical Specialty:

Clinical Chemistry

Predicate Device:

Bio-Rad Liquicheck™ Urinalysis Control
Bio-Rad Laboratories, Hercules, CA 94547 USA
510(k) Number: K070848

Chek-Stix® Positive and Negative Control Strips for Urine Chemistry
Siemens Healthcare Diagnostics Inc., Tarrytown NY 10591 USA
510(k) Number: K931467 (Original submitter: Heraeus Kulzer Inc.)

Description:

The Mission Liquid Urine Control and Mission Liquid Diptube Urine Control are prepared from simulated human urine with purified chemicals, constituents of animal origin, preservatives and stabilizers. The controls are available in two levels, ready to use liquid format packaged in dropper bottles under the brand name Mission Liquid Urine Control and in diptube containers under the brand name Mission Liquid Diptube Urine Control. The results of the Mission Liquid Urine Control and Mission Liquid Diptube Urine Control are compared to the lot-specific expected values listed in the package insert to ensure the consistent performance of Mission Urinalysis Reagent Strips and Mission Urine Analyzers.

The Mission Dry Strip Urine Control are firm plastic strips onto which reagent areas are affixed. The negative level strips have five reagent areas containing one or more synthetic ingredients. When placed in a measured quantity of distilled or deionized water, the ingredients dissolve out of the reagent areas to produce a Level 1 Control Solution. The Level 2 strips have six reagent areas affixed. The ingredients on the positive level strips dissolve out to produce a Level 2 Control Solution. The results of the Mission Dry Strip Urine Control are compared to the lot-specific expected values listed in the package insert to ensure the consistent performance of Mission Urinalysis Reagent Strips and Mission Urine Analyzers

Intended Use:

The Mission Liquid Urine Control, Mission Liquid Diptube Urine Control and Mission Dry Strip Urine Control are assayed urine controls intended for use in validating the precision of visual and analyzer reading of urinalysis for one or more of the following analytes: Ascorbic acid, Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes. It is intended for professional in vitro diagnostic use only.

Technological Characteristics:

Feature	Specifications	
	Mission Liquid Urine Control; Mission Liquid Diptube Urine Control	Mission Dry Strip Urine Control
Format	Liquid, ready to use	Dry, reconstituted with DI water
Levels	2	2
Storage Temperature	35-46°F (2-8°C)	35-86°F (2-30°C)
Shelf Life	24 months 2-8°C	24 months at 2-30°C
Open Stability	24 months at 2-8°C 30 days at 15-30°C	3 months at 2-30°C; 8 hours after reconstituted
Maximum No. Tests per Unit	20 tests (diptube only)	12 tests per reconstituted control
Preservatives	0.02% Proclin	0.02% Proclin
Analytes	Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes and Ascorbic Acid	Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes and Ascorbic Acid

Comparison to Predicate Devices:

The Mission Liquid Urine Control and Mission Liquid Diptube Urine Control are substantially equivalent to the Bio-Rad Laboratories Liquicheck Urinalysis Control.

Feature	Mission Liquid Urine Control; Mission Liquid Diptube Urine Control	Bio-Rad Laboratories Liquicheck Urinalysis Control
Similarities		
Intended Use	For use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in the package insert	Same
Form	Liquid	Same
Levels	2	Same
Storage Temperature	2-8°C	Same
Differences		
Matrix	Liquid matrix solution	Human urine
Open Vial	24 months at 2-8°C 30 days at 15-30°C	30 months at 2-8°C 30 days at room temperature (18-25°C)
Shelf Life	24 months at 2-8°C	30 months at 2-8°C
Packaging Configuration	Dropper, diptube	Dropper
Analytes	Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes and Ascorbic Acid	Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes, Creatinine, Microalbumin, Microscopics (RBC, WBC, Crystals), Osmolality, Pregnancy (hCG), Protein-to-Creatinine Ratio

The Mission Dry Strip Urine Control is substantially equivalent to the Siemens Healthcare Diagnostics Inc. Chek-Stix Positive and Negative Control Strips for Urine Chemistry.

Feature	Mission Dry Strip Urine Control	Siemens Healthcare Diagnostics Chek-Stix Positive and Negative Controls Strips for Urine Chemistry
Similarities		
Intended Use	For use as an assayed quality control urine to monitor the precision of urinalysis test procedures for the analytes listed in the package insert	Same
Form	Dry strip	Same
Levels	2	Same
Maximum Tests per unit	12	Same
Incubation Time	30 minutes	Same
Analytes	Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite, Leukocytes and Ascorbic Acid	Same
Differences		
Storage Temperature	2-30°C	15-30°C
Open Vial	3 months at 35-86°F (2-30°C)	18 months at 15-30 °C
Shelf Life	24 months at 2-30°C	18 months at 15-30 °C
Stability after Reconstitution	8 hours for all parameters	8 hours for all parameters except 3 hours for bilirubin

Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Guidance document included the FDA "Guidance for Industry and FDA Staff Assayed and Unassayed Quality Control Material, Issued on June 7, 2007"

Laboratory Testing:

The performance characteristics of the Mission Liquid Urine Control, Mission Liquid Diptube Urine Control and Mission Dry Strip Urine Control were evaluated by the following studies: matrix effects, control value assignment, temperature flexibility, humidity effect, lighting effect, number of dip times (diptube and dry strip only), incubation time (dry strip only), and shelf life and stability.

Discussion of Clinical Tests Performed:

Not Applicable.

Conclusion:

The laboratory testing demonstrates that the Mission Liquid Urine Control, Mission Liquid Diptube Urine Control and Mission Dry Strip Urine Control are safe, accurate and easy-to-use. It also demonstrates that the Mission Liquid Urine Control, Mission Liquid Diptube Urine Control and Mission Dry Strip Urine Control are substantially equivalent to the Bio-Rad Laboratories Liquicheck Urinalysis Control and Siemens Healthcare Diagnostics Inc. Chek-Stix Positive and Negative Control Strips for Urine Chemistry, currently sold on the U.S. market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FEB 0 2 2011

ACON Laboratories, Inc.
c/o Richard Lenart
Regulatory Affairs Manager
10125 Mesa Rim Road
San Diego, CA 92121 USA

Re: k103387
Trade Name: Mission Liquid Urine Control, Mission Liquid Diptube Urine Control, Mission Dry Strip Urine Control
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, Reserved
Product Codes: JJW
Dated: January 13, 2011
Received: January 18, 2011

Dear Mr. Lenart:

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 Parts 801 and 809), 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 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/cdrh/industry/support/index.html.

Sincerely yours,

Courtney 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

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K103387

Device Name: Mission® Liquid Urine Control
Mission® Liquid Diptube Urine Control
Mission® Dry Strip Urine Control

Indications for Use:

The Mission Liquid Urine Control, Mission Liquid Diptube Urine Control and Mission Dry Strip Urine Control are assayed urine controls intended for use in validating the precision of visual and analyzer reading of urinalysis for one or more of the following analytes: Ascorbic acid, Glucose, Bilirubin, Ketone (Acetoacetic acid), Specific Gravity, Blood, pH, Protein, Urobilinogen, Nitrite and Leukocytes. It is intended for professional in vitro diagnostic use only.

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

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