k131993

510(k) Summary
Multichem U

OCT 15 2013

1.0 Submitter and Contact:

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2.0 Date Submitted:

June 28, 2013

3.0 Device Identification

Proprietary Names:	Multichem U
Common Name:	Multi-Analyte Controls, (Assayed and unassayed)
Classification:	Class 1, Reserved
Product Code:	JJY
Regulation Number:	21 CFR 862.1660

4.0 Legally Marketed Predicate Device

Candidate(s)	Predicate	Manufacturer	Document Number
Multichem U	Liquichek™ Urine Chemistry Control	Bio-Rad Laboratories	K020817

The Multichem U Control is substantially equivalent to the Bio-Rad product listed above, currently in commercial distribution.

5.0 Device Description

Technopath has developed two levels of a urine control prepared from human urine to which purified biochemical material (extracts of human and animal origin), chemicals, drugs/preservatives and stabilizers have been added. The control is used in liquid form for convenience. The two levels of control are available to allow performance monitoring within the analytical range.

The following kit configurations are available:

Model UC 201A.10 with Level 1 control; 15 vials with 10 mL contents
Model UC 202A.10 with Level 2 control; 15 vials with 10 mL contents
Model 05P80-10, with Bi-Level controls; 6 Level 1 vials and 6 Level 2 vials; vials have 5mL contents

The serum from each donor contributing urine for this material has been tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV, and nonreactive for HBsAg.

6.0 Intended Use

Multichem U is intended for use as an assayed urine quality control to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. Two levels of Controls (Level 1 and Level 2) are supplied in liquid form.

The following analytes are listed in the package insert: Amylase, Calcium, Chloride, Creatinine Enzymatic, Creatinine Picrate, Glucose, Magnesium, Microalbumin, Phosphorous, Potassium, Sodium, Urea Nitrogen, Uric Acid, and Urinary Protein.

7.0 Comparison to the Predicate

Multichem U control claims to be substantially equivalent to Liquichek™ Urine Chemistry Control. The control has same/similar design and modes of operation. The key features are summarized in the following table.

Characteristics	Predicate Device: Liquichek™ Urine Chemistry Control	Proposed Device: Multichem U
Similarities		
Intended Use:	Liquichek™ Urine Chemistry Control is intended for use as an assayed quality control urine to monitor the precision of laboratory procedures listed in the package insert.	Multichem U is intended for use as an assayed urine quality control to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. Two levels of Controls (Level 1 and Level 2) are supplied in liquid form.
Form:	Liquid	Liquid
Matrix:	Human urine based	Human urine based
Storage (Closed/Shelf-Life)	2° to 8°C Until expiration date	2° to 8°C Until expiration date
Open Vial	30 days at 2° to 8°C	30 days at 2° to 8°C
Differences		
Analytes (Assayed)	Contains: Amylase Calcium Chloride Cortisol Creatinine	Contains: Amylase Calcium Chloride Creatinine Enzymatic Creatinine Picrate

Characteristics	Predicate Device: Liquichek™ Urine Chemistry Control	Proposed Device: Multichem U
	Glucose	Glucose
	hCG (Qualitative)	
	Magnesium	Magnesium
	Microalbumin	Microalbumin
	Osmolality	
	pH	
	Phosphorus	Phosphorous
	Potassium	Potassium
	Pregnancy	
	Protein-Total	
	Sodium	Sodium
	Specific Gravity	
	Urea	
	Urea Nitrogen	Urea Nitrogen
	Uric Acid	Uric Acid
		Urinary Protein

8.0 Performance Characteristics

8.1 Value Assignment Summary

Value assignment testing was performed utilizing internal procedures and protocols to determine typical values that would be seen for the product across Abbott ARCHITECT c8000® clinical chemistry systems with the associated reagent test systems. For the Multichem U control, 2 reagent lots and 2 calibrator lots were used to incorporate reagent and calibrator variation where available. 2 replicates from 16 runs were performed to give a total of 32 data points. Distinct runs, with minimum gaps of 2 hours were performed and a minimum of 8 calibration events were performed to incorporate variation from calibration and environmental sources. Value assignment ranges were established at the pre-determined criteria of 20% around the grand mean to most analytes; however, a 10% range is applied to the Potassium, Sodium and Chloride.

8.2 Stability Testing Summary

Stability studies have been performed to determine the open vial stability and shelf-life for this control. For open vial stability, Technopath utilized internal procedures and two protocols methods (Classical [Forward] method and Isochronous - Staggered Start [Backwards / Back-ended] method) from CLSI EP25A entitled "Evaluation of Stability of *In Vitro* Diagnostic Reagents." To minimize variation, where possible, one lot of reagent, calibrator and reference/control was used for the entire study, per analyte. Testing was performed over multiple days on 1 Abbott ARCHITECT c8000® clinical chemistry system with the associated reagent test systems. All Multichem U analytes from open vial and freshly thawed vial samples were tested in replicates of 3 at each time point. Multiple time points were tested and the point of failure was determined by the maximum allowable drift (degradation), which was determined to be analyte specific.

Product claims are as follows:

Open Vial Stability: 30 days at 2° - 8° C

Accelerated testing was carried out utilizing CLSI EP25A in order to support a shelf-life storage claim of 24 months at 2° to 8°C. The accelerated testing utilized three lots of controls. All data was generated using the Abbott ARCHITECT c8000® clinical chemistry system with the associated reagent test systems. For the Multichem U control, the Drift Limit was determined to be 10%. These results concluded that the Multichem U Controls product is predicted to be stable for in excess of 24 months when stored at 2° - 8° C. The real-time testing is not available at this time, but is on-going and will be performed on a minimum of 3 lots.

8.3 Traceability Summary

The analytes contained within the Multichem U control (Level 1 and 2) are found endogenously in the base urine matrix and are adjusted to the required concentration through use of commercially available sources. Technopath does not claim traceability to higher order reference materials or methods.

9.0 Conclusion:

The conclusions drawn from the nonclinical tests (discussed above) demonstrate that the Multichem U control is as safe, as effective, and performs as well as the predicate device. The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

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

October 15, 2013

Techno-Path Manufacturing Ltd.
C/O Stephanie Garth
Global Compliance Plus
325 Big Elm St.
HIGHLAND VILLAGE TX 75077

Re: K131993
Trade/Device Name: Multichem U
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, reserved
Product Code: JJY
Dated: August 23, 2013
Received: August 26, 2013

Dear Ms. Garth:

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 Parts 801 and 809); 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 regulations (21 CFR Parts 801 and 809), please contact 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. 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 Form

510(k) Number (if known): k131993

Device Name: Multichem U

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- Amylase
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- Glucose
- Magnesium
- Microalbumin
- Phosphorous
- Potassium
- Sodium
- Urea Nitrogen
- Uric Acid
- Urinary Protein

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 OF 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

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