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

March 31, 2017

TECHNO-PATH MANUFACTURING
BERND HASS
HEAD OF QUALITY AND REGULATORY AFFAIRS
FORT HENRY BUSINESS PARK
BALLINA, CO. TIPPERARY
IRELAND

Re: K162530
Trade/Device Name: Multichem IA Plus
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJY
Dated: March 3, 2017
Received: March 3, 2017

Dear Bernd Hass:

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 Industry and Consumer Education 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" (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 Industry and Consumer Education 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,

Kellie B. Kelm -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k162530

Device Name
Multichem IA Plus

Indications for Use *(Describe)*
For In Vitro Diagnostic use only.
Multichem IA Plus is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
Multichem IA Plus assayed Control

1.0 Submitter:

Bernd Hass

Head of Quality and Regulatory Affairs

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Ireland

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2.0 Date Sumbitted:

31st March 2017

3.0 Device Identification

Submission Type: Abbreviated 510(k)

Abbreviated 510(k) number: k162530

Basis: Device Modification

Device Name: Multi-Analyte Controls, All Kinds (Assayed)

Trade Name: Multichem IA Plus

Model Number: IA300 A, 05P76-10 (IA310A, IA311A, IA312A, IA313A)

Classification Regulation: CFR 862.1660

Class: Class I, reserved

Panel: Clinical Chemistry

Generic Category: Quality Control Material (Assayed and Unassayed)

Product Code: JJY

4.0 Legally Marketed Predicate Device

Candidate	Predicate	Manufacturer	Document number
Multichem IA Plus	Multichem IA Plus	Technopath Manufacturing	K132091

The Multichem IA Plus control is substantially equivalent to the predicate, product listed above, currently in commercial distribution.

5.0 Device Description

The Multichem IA Plus control is prepared from human serum 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 use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. Three levels of control are available to allow performance monitoring within the clinical range.

Multichem IA Plus controls are prepared from human serum with added constituents of human and animal origin, chemicals, therapeutic drugs, stabilizers and preservatives. The control is provided in liquid form for convenience.

Each donor unit used in the preparation of the control material was tested by United States Food and Drug Administration (FDA) approved methods and found to be negative for antibodies to HIV and HCV, and non-reactive for HBsAg.

The following kit configurations are available:

Multichem IA Plus

Model IA310A (Trilevel) with Level 1, 2 & 3 control; 12 vials with 5 mL contents

Model 05P56-10 (Trilevel) with Level 1, 2 & 3 control; 12 vials with 5 mL contents

Model IA311A with Level 1 control; 12 vials with 5 mL contents

Model IA312A with Level 2 control; 12 vials with 5 mL contents

Model IA313A with Level 3 control; 12 vials with 5 mL contents

6.0 Intended Use

For In Vitro Diagnostic use only.
Multichem IA Plus is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.

7.0 Comparison to the Predicate

Multichem IA Plus Control has been updated since the original 510k submission. The key features are summarized in the following table:

Characteristics	**Predicate Device: Multichem IA Plus Assayed Control k132091**	**Proposed Device: Multichem IA Plus Assayed Control**
Similarities		
Intended Use:	Multichem IA Plus is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.	Multichem IA Plus is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Form:	Liquid, Frozen	Liquid, Frozen
Matrix:	Processed Human Serum	Processed Human Serum

Changes / Differences		
Analytes (Assigned)	Alpha Fetoprotein BNP CA 125 CA 15-3 CA 19-9 Carbamazepine Carcinogenic Embryonic Antigen CK-MB Cortisol C-Peptide DHEA Sulfate Digoxin Estradiol Ferritin Folate Follicle Stimulating Hormone Gentamicin Homocysteine Human Chorionic Gonadotropin Insulin Leutinizing Hormone Myoglobin Phenobarbital Phenytoin Progesterone Prolactin Prostate Specific Antigen, Total PTH Intact Testosterone Theophylline Thyroid Stimulating Hormone Thyroxine, Free (free T4) Triiodothyronine, Free (free T3) Troponin I Valproic Acid Vancomycin Vitamin B12 Anti - TPO Anti-thyroglobulin SHBG PSA (free) T Uptake	Alpha Fetoprotein BNP CA 125 CA 15-3 CA 19-9 Carbamazepine Carcinogenic Embryonic Antigen CK-MB Cortisol C-Peptide DHEA Sulfate Digoxin Estradiol Ferritin Folate Follicle Stimulating Hormone Gentamicin Homocysteine Human Chorionic Gonadotropin Insulin Leutinizing Hormone Myoglobin Phenobarbital Phenytoin Progesterone Prolactin Prostate Specific Antigen, Total PTH Intact Testosterone Theophylline Thyroid Stimulating Hormone Thyroxine, Free (free T4) Triiodothyronine, Free (free T3) Troponin I Valproic Acid Vancomycin Vitamin B12 Anti - TPO Anti-thyroglobulin SHBG PSA (free) T Uptake

	T3 (total) T4 (total) 25OH Vitamin D IgE - - - - - - - - - - - - -	T3 (total) T4 (total) 25OH Vitamin D IgE Acetaminophen ACTH Amikacin Calcitonin Human Growth Hormone Lithium Salicylate Thyroglobulin Tobramycin Estriol, Free EPO NT Pro BNP Troponin T
Storage (Unopened) Shelf Life	30 Months @ -20°C to -80°C	36 Months @ -20°C to -80°C
Storage Open Vial	10 days, with the following exceptions: BNP = 1 hour C-Peptide = 7 days Folate = 2 days Homocysteine = 7 days PTH Intact = 4 days Troponin I = 4 days 25OH Vitamin D = 4 days	10 days, with the following exceptions: BNP = 1 hour C-Peptide = 7 days Folate = 2 days Homocysteine = 7 days PTH Intact = 4 days Troponin I = 4 days 25OH Vitamin D = 4 days ACTH = 8 hours Calcitonin = 7 days Troponin T = 7 days

8.0 Summary of Performance Data

A number of changes have been introduced for the Technopath Multichem IA Plus Control as outlined above. The differences have been tested to ensure that they do not present any new safety or effectiveness concerns. Stability studies have been performed to determine the open vial stability and shelf life for this control.

Product claims are as follows:

Open Vial Stability:

- 10 days at 2 to 8°C for all analytes with the following exceptions
- 7 days at 2 to 8°C = C-Peptide, Homocysteine, Calcitonin & Troponin T.
- 4 days at 2 to 8°C = PTH Intact, Troponin I & 25OH Vitamin D
- 2 days at 2 to 8°C = Folate
- 8 hours at 2 to 8°C = ACTH
- 1 hour at 2 to 8°C = BNP

Storage (Unopened)/Shelf-Life:

- 36 months at -20° to -80°C

In conclusion, that data and the submission provide the summary data necessary to demonstrate substantially equivalent to the referenced predicate already in commercial distribution. Additional supporting data is retained on file at Techno-path Manufacturing, Ltd. The summary of safety and effectiveness is being submitted in accordance with the requirements of the Safe Medical Device Act of 1990 and the implementing regulation 21 CFR 807.92.