



Food and Drug Administration
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TECHNOPATH MANUFACTURING
BERND HASS
HEAD OF QUALITY AND REGULATORY AFFAIRS
FORT HENRY BUSINESS PARK
BALLINA CO. TIPPERARY, IRELAND

October 26, 2016

Re: K162514

Trade/Device Name: Multichem A1c
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: September 5, 2016
Received: September 26, 2016

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,


Katherine Serrano -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)

K162514

Device Name
Multichem A1c

Indications for Use (Describe)

Multichem A1c control is intended for use as an assayed quality control to monitor the precision of laboratory testing procedures for the analyte, HbA1c, as 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Multichem A1c (Assayed) Control

1.0 Submitter:

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2.0 Date Submitted:

26st October 2016

3.0 Device Identification

Proprietary Names: Multichem A1c
 Common Name: Quality Control material, single (specified) analytes
 Classification: Class 1, Reserved
 Product Code: JJX
 Regulation Number: 21 CFR 862.1660

4.0 Legally Marketed Predicate Device

Candidate	Predicate	Manufacturer	Document number
Multichem A1c	CONE-TROL Hemoglobin A1c Control set	Cone Bioproducts	K121534

The Multichem A1c control is substantially equivalent to the Cone Bio product listed above, currently in commercial distribution.

5.0 Device Description

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. A minimum of two levels of control are available to allow performance monitoring within the clinical range of HbA1c assay method. Multichem A1c control is prepared from human red blood cells with added chemicals and stabilizers. The control is provided in liquid form for convenience.

The following kit configurations are available:

Multichem A1c

Model HB000A (bi-level) with Level 1 & 2 control; 12 vials with 1 mL contents

Model HB001A with Level 1 control; 12 vials with 1 mL contents

Model HB002A with Level 2 control; 12 vials with 1 mL contents

Model HB000M (bi-level minipak) with Level 1 & 2 control; 1 vial with 1 mL contents

Model HB000T (bi-level) with Level 1 & 2 control; 12 vials with 1 mL contents

Model HB001T with Level 1 control; 12 vials with 1 mL contents

Model HB002T with Level 2 control; 12 vials with 1 mL contents

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.

6.0 Intended Use

Multichem A1c control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analyte, HbA1c as listed in the package insert.

7.0 Comparison to the Predicate

Multichem A1c control claims to be substantially equivalent to CONE-TROL Hemoglobin A1c control set. The controls have same/similar design and modes of operation. The key features are summarized in the following table.

Characteristics	Predicate Device: CONE-TROL Hemoglobin A1c Control Set	Proposed Device: Multichem A1c
Intended Use:	CONE-TROL Hemoglobin A1c Control Set is intended for use as a quality control material to monitor the performance and precision of Hemoglobin A1c determination methods.	Multichem A1c control is intended for use as an assayed quality control material to monitor the precision of laboratory testing procedures for the analyte, HbA1c as listed in the package insert.
Analytes	A1c	A1c
Form:	Liquid	Liquid

Matrix:	Human Blood, Stabilisers, and preservatives	Human Blood and Stabilisers, and preservatives
Storage	-20°C	-20°C to -80°C
Thawed and Open	Open Vial Stability (2°C -8°C) 180 days	Open Vial Stability (2°C -8°C) 30 days
Shelf Life	2 years	1 years (12 mth)

8.0 Value assignment process

The value assignment performance outlined here, was performed using a single analyser with single reagent and calibrator lot. Variability was introduced by performing the testing over multiple days.

Target assigned here were performed on the, Tosoh, Beckman and Trinity analysers, independently, with values claimed on each platform. The control target is the mean value of all the replicates generated on the specified instrument. The number of replicates performed is detailed in the below tables. No data points were excluded. Target values assigned have to be with the following acceptance specifications:

LEVEL 1

			Acceptance Ranges	
ANALYTES	Analyser Reported Units	TARGET	LOW	HIGH
% HbA1c	(DCCT/NGSP)	5.50	4.00	7.00
A1c	IFCC mmol/mol	36.6	20.2	53.0

LEVEL 2

ANALYTES	Analyser Re-ported Units	TARGET	Acceptance Ranges	
			LOW	HIGH
% HbA1c	(DCCT/NGSP)	10.5	8.00	13.0
A1c	IFCC mmol/mol	91.3	63.9	119

The control ranges are set based on a review of the imprecision (3 x Standard Deviation) of the (instrument specific) value assignment data with a minimum applied range of $\pm 10\%$.

Lot A0004150

Tosoh - Value Assignment testing was performed over 5 days with n = 45 replicates

Hemoglobin A1c	% Range	Unit	Level 1		Level 2	
			Target	Range	Target	Range
Tosoh (G8)	10%	NGSP (%) mmol/mol	5.97	5.37 - 6.57	10.2	9.18 - 11.2
			41.8	35.2 - 48.3	87.6	76.8 - 98.9

Beckman - Value Assignment testing was performed over 5 days with n = 23 replicates

Hemoglobin A1c	% Range	Unit	Level 1		Level 2	
			Target	Range	Target	Range
Beckman (AU 5800)	25%	NGSP (%) mmol/mol	5.35	4.01 - 6.69	9.91	7.43 - 12.4
			35.0	20.3 - 49.6	84.9	57.7 - 112

Trinity Biotech - Value Assignment testing was performed over 5 days with n = 15 replicates

Hemoglobin A1c	% Range	Unit	Level 1		Level 2	
			Target	Range	Target	Range
Trinity Biotech Premier (Hb9210)	10%	NGSP (%) mmol/mol	5.02	4.52 - 5.52	10.5	9.47 - 11.6
			31.4	25.9 - 36.8	91.5	80.0 - 103

9.0 Summary of Performance Data

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:

30 days at 2°C to 8°C

Storage (Closed/Shelf-Life):

-20°C to -80°C until expiration date.

The submission provides the summary data necessary to demonstrate substantial equivalence to the reference predicate. 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.

Stability (Open Vial)

The Multichem A1c (Assayed) controls were evaluated using an Isochronous (Staggered Start [Backwards / Back-ended]) protocol design as per CLSI EP25-A.

Open Vial testing was performed (at 2°C -8°C) by testing vials which were thawed and opened for pre-defined durations (test vials) against a freshly thawed, unopened vial (reference vials). All analytes from open vial and freshly thawed vial samples were tested in replicates of 3 at each time-point.

Acceptance criteria: Maximum Allowable Degradation / Drift Limit <10%

Stability (Closed Vial)

Accelerated Stress Test:

An in-house study was performed which shows that an accelerated model of 6.5 hours @ 37°C is comparable with ≥ 20 month real-time data and therefore represents a suitable model for the prediction of a shelf-life of (significantly beyond) 12 months.

Testing, using this accelerated model, was performed on 3 separate HbA1c Control lots. The A1c % value of the stressed vials was verified versus the A1c % value of a fresh (unstressed) sample. All samples were tested in duplicate.

Acceptance Criteria: Drift Limit of ≤ 10%

The % shift in HbA1c value is calculated using the following formula.

$$\% \text{ shift in A1c} = [(\text{mean stressed value \%} / \text{mean fresh value \%}) - 1] \times 100$$

Testing supports a shelf life of ≥ 12 months.

A real time stability test program has been implemented at Technopath Manufacturing Ltd.

Stability is assessed by testing the HbA1c analyte at specific time points over the proposed shelf life of the product. Testing will be completed for a minimum of 3 lots of the controls at each time point using product stored at both -20°C and at -80°C .

Acceptance Criteria: Drift Limit of $\leq 10\%$

10.0 Conclusion.

The Submitted information in this premarket notification is complete and supports a substantial equivalence decision.