JUN 2 0 2012

SECTION V

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number: k i K121534

Submitter:
Cone Bioproducts
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Contact Person:

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Project Manager
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Preparation Date:

June 13, 2012

Device Information:

Device Classification Name:	Single Analyte Controls (Assayed and Unassyed)
Proprietary Name:	CONE-TROL Hemoglobin A1c Control Set
Regulation Number:	21 CFR§862.1660
Product Code:	JJX
Regulatory Class:	Class I

Predicate Devices:

The CONE-TROL Hemoglobin A1c Control Set is substantially equivalent to Cone Bioproducts' HbA1c Linearity Set (k052010) for its stated intended use.

Device Description:

The CONE-TROL Hemoglobin A1c Control Set is prepared from human blood to which chemicals, preservatives, and stabilizers are added. The control is provided in liquid form for user convenience.

Intended Use:

CONE-TROL Hemoglobin A1c Control Set is intended for use as quality control material to monitor the performance and precision of Hemoglobin A1c determination methods.

Comparison to Predicate Device(s):

CONE-TROL Hemoglobin A1c Control Set is substantially equivalent to Cone Bioproducts' HbA1c Linearity Set, (k052010) for its stated intended use.

Device Characteristics	Subject Device	Predicate Device(s) k052010
Intended Use	CONE-TROL Hemoglobin A1c Control Set is intended for use as quality control material to monitor the performance and precision of Hemoglobin A1c determination methods.	HbA1c Linearity Set is intended for use as quality control material to monitor the linearity throughout the reportable range of Hemoglobin A1c assays using protocols established in individual laboratories.
Analyte	A1c	A1c
Methodology	Compatible with Immunoassay and HPLC HbA1c test methods.	Compatible with Immunoassay and HPLC HbA1c test methods.
Matrix	Human Blood, stabilizers, and preservative.	Human Blood, stabilizers, and preservative.
Control Form	Liquid	Liquid
Levels	1-2	1-4
Storage	-20°C	-20°C
Stability	Unopened vial stability (-20°C): 2 Years Unopened vial stability (2-8°C): 180 days Opened vial stability (2-8°C): 180 days	Unopened vial stability (-20°C): 2 Years Opened vial stability (2-8°C): 14 days

Summary:

Value Assignment:
Levels 1 and 2 are prepared so that Level 1 meets the clinically normal range of HbA1c, and Level 2 meets the clinically abnormal range of HbA1c on the manufacturer's instrument. Levels 1 and 2 are assayed in triplicate on the applicable instrument system. When the recovery falls within ±10% of the target concentration, the CONE-TROL Hemoglobin A1c Control Set is labeled and filled. QC testing for value assignment is performed for Levels 1 and 2 of control. Two vials are assayed in triplicate over a minimum of 2 days and maximum of 7 day period on the Immunoassay or HPLC test method for which the product is designed. A minimum of 6 data points for each level is required for value assignment. One instrument may be used if used on two different days or by two different operators. The mean, standard deviation and coefficient of variance is determined for each instrument for each level of control.

CLOSED VIAL STABILITY
The shelf life for CONE-TROL HbA1c Control Set has been determined based upon accelerated stability studies to be confirmed by real time stability studies. The expiration for CONE-TROL HbA1c Control Set is 2 years at -20°C and for 180 days at 2-8°C from the date of manufacture.

The product stability has been extrapolated from accelerated studies with elevated temperatures and will be confirmed by real time studies. Hemoglobin A1c concentrations were analyzed using the Tosoh G7 HPLC Analyzer. Vials were stored at -20°C and 37°C and values were obtained between 0 and 30 hours.

The Q Rule Table based on the Arrhenius Equation was used to estimate the shelf life during the accelerated stability study. The Q Rule states that a product's degradation rate decreases by a constant factor (Q=4) every 10°C decrease in temperature. For the test point to be valid the analyte activity must fall ± 10% from the initial value.

Table VII-1: Accelerated Closed Vial Stability of CONE-TROL Hemoglobin A1c Control Set at 37°C

Analyte	Initial Value	Concentration at 30 hours	Percent Change	Concentration Range Accepted by Company
HbA1c-Level 1	5.3%	5.4%	1.89%	4.2-6.4%
HbA1c-Level 2	10.8%	10.8%	0%	8.6-13.0%

To date, real time stability studies confirm the accelerated stability studies through 210 days. Closed Vial real time stability will be monitored throughout the life of the product. Closed Vial stability data will be collected at six month intervals. For the test point to be valid the analyte activity must fall ± 10% from the initial value.

Table VII-2: Real Time Closed Vial Stability at -20°C

Analyte	Initial Value	Concentration at 210 days	Percent Change	Concentration Range Accepted by Company
HbA1c-Level 1	5.3%	5.4%	1.89%	4.2-6.4%
HbA1c-Level 2	11.9%	12.1%	1.68%	9.5-14.3%

Based on the data given in Table VII-1, CONE-TROL Hemoglobin A1c Control Set will be stable for 2 years when stored at -20°C as specified in the product insert.

OPEN VIAL STABILITY

The open vial, 2-8°C stability of CONE-TROL Hemoglobin A1c Control Set has been determined from real time stability testing. HbA1c concentrations were determined using a Tosoh G7 HPLC Analyzer. CONE-TROL Hemoglobin A1c Control Set was stored as described in the package insert. Values for Hemoglobin A1c were collected through 210 days.

Table VII-3: Open Vial Stability of CONE-TROL Hemoglobin A1c Control Set at 2-8°C

Analyte	Initial Value	Concentration at 210 days	Percent Change	Concentration Range Accepted by Company
HbA1c-Level 1	5.3%	5.0%	5.7%	4.2-6.4%
HbA1c-Level 2	11.9%	11.5%	3.4%	9.5-14.3%

Based on the data presented in Table VII-3, at the present time, CONE-TROL Hemoglobin A1c Control Set will be given an expiration date of 180 days when stored at 2-8°C as described in the package insert.

Substantial Equivalence:
The information provided in this pre-market notification demonstrates CONE-TROL Hemoglobin A1c Control Set is substantially equivalent to Hemoglobin A1c Linearity Set (k052010). Substantial equivalence was demonstrated through comparison of intended use and physical properties to the commercially available and analytical predicate device. The information supplied in this pre-market notification provides reasonable assurance that the CONE-TROL Hemoglobin A1c Control Set is safe and effective for its stated intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Cone Bioproducts
Ms. Gail Schievelbein
Project Manager
1012 N. Austin St.
Seguin, TX 78155

JUN 20 2012

Re: k121534
Trade/Device Name: CONE-TROL Hemoglobin Alc Control Set
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: Class I, reserved
Product Code: JJX
Dated: May 2, 2012
Received: May 24, 2012

Dear Ms. Schievelbein:

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 class II (Special Controls), 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 Part 801), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121534

Device name: CONE-TROL Hemoglobin A1c Control Set

Indications for Use:

CONE-TROL Hemoglobin A1c Control Set is intended for use as quality control material to monitor the performance and precision of Hemoglobin A1c determination methods.

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 Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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