510K Summary

K060570

Prepared: 2/22/2006

Submitted by: Evy K. Johnson
Establishment Address: Compass Bioscience
1850 Evergreen Street
Duarte CA 91010
phone: 626.359.9645
fax: 626.359.7697

APR 13 2006

Establishment Registration Number: 2032652

Contact Person: Dr. Carter Grandjean

Proprietary (Trade) Name:

Common Name: Hemoglobin A1c Assayed Control

Classification Name: Single Analyte Controls, All Kinds (assayed and unassayed) 75 JJX

Classification: Class I

Substantial Equivalence:

The Compass Bioscience Hemoglobin A1c Control is supplied as frozen liquid in two levels and consists of a human whole blood matrix adjusted to target concentrations of glycated hemoglobin (HbA1c) and containing preservatives and stabilizers. Assayed values are determined from interlaboratory data.

The Compass Bioscience controls are substantially equivalent to other such controls in general use, such as the **MAS Diabetes Control,** sold by Medical Analysis Systems, which is supplied liquid in two levels as a human whole blood matrix adjusted to specific concentrations of glycated hemoglobin.

Description:

Hemoglobin A1c Assayed Controls are supplied in two levels, 3 x 1 mL each level per box . The controls are supplied as a ready-to-use frozen liquid, requiring no reconstitution or dilution. They are prepared in a human whole blood matrix adjusted to target concentrations of HbA1c. Stabilizers and preservatives have been added to inhibit microbial growth.

Intended Use:

The Compass Bioscience Hemoglobin A1c Assayed Controls are intended for use as quality control materials to assess the accuracy and precision of assay procedures for HbA1c used in individual laboratories.

Technological Characteristics Compared to Predicate Devices:

The Compass Bioscience control product employs a similar matrix and constituent formulation to the equivalent predicate device listed above: human whole blood matrix with adjusted glycated (HbA1c) levels containing stabilizers and preservatives. The Compass Bioscience Control also has similar storage and stability requirements as the equivalent devices.

Performance Characteristics:

The closed vial stability claim made for this product is 2 years when stored at -15° C to -25° C, based on accelerated stability studies.[2] The Hemoglobin A1c control was stored at 2-8°C to simulate 2 years storage at -15°C to -25° C. An increase or decrease of >10% of analyte recovery compared to the initial test value ± the highest allowable instrument/reagent imprecision was used as the analyte failure criterion for determining shelf life. Real time stability testing is ongoing on multiple lots of product.

The closed vial stability claim for this product when stored at 2-8° C is 12 months. Accelerated stability testing at 20 - 25° C was used to determine the closed vial refrigerated shelf life. The Hemoglobin A1c Control was stored at 20 - 25° C and the recovery (vs. day 0) was measured in intervals of 7 days. The product passed stability if its recovery was within ±10% of the day 0 value after 35 days of storage at 20 - 25° C.

The open vial stability claim for this product is 90 days when stored at 2 - 8° C. Real time testing of vials opened, warmed to room temperature, sampled, and returned to the refrigerator, and re-used at various intervals in the same manner was performed and measured against freshly opened vials. The product passed stability if its recovery was within ±10% of the Day 0 value after 88 days of storage at 2 - 8° C. Multiple lots of product were tested with no significant difference in performance.

The open vial stability claim for this product is 7 days when stored at 20 – 25° C (Room Temperature). Real time testing of vials opened, sampled, re-capped, and re-used at various intervals in the same manner was performed and measured against freshly opened vials. The product passed stability if its recovery was within ±10% of the day 0 value after 10 days of storage at 20 - 25° C. Multiple lots of product were tested with no significant difference in performance.

The equivalent predicate device, MAS Diabetes Control, claims a 2 year shelf life for storage at -20° C and a 14 day opened/closed vial stability at refrigerated (2 - 8° C) storage.

Assayed Values

Assay values were established from interlaboratory data using instrument manufacturers' reagents. Mean values and expected ranges for the listed lots of controls were calculated from reagent lots available at the time of assay.

---

[2] L. Kennon, Stability Prediction Model, Journal of Pharmaceutical Sciences 53:7, 815-818, 1964.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 13 2006

Ms. Evy Johnson
Chief Operating Officer
Compass Bioscience
1850 Evergreen Street
Duarte CA, 91010

Re: k060570
Trade/Device Name: Hemoglobin A1c Assayed Control
Regulation Number: 21 CFR§ 862.1660
Regulation Name: Quality control material
Regulatory Class: Class I
Product Code: JJX
Dated: February 28, 2006
Received: March 7, 2006

Dear Ms. Johnson:

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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060570

Device Name: Hemoglobin A1c

Indications For Use:

The Compass Bioscience Hemoglobin A1c Control is to be used as a quality control material to assess the accuracy and precision of laboratory test methods used to measure Hemoglobin A1c levels. It is intended to validate the measurement of Hemoglobin A1c in patient samples.

Two levels of control are provided to allow the performance of the analyte test methods to be monitored within the clinically significant range.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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)

Carol C. Benson
Division Sign-Off

Office of in Vitro Diagnostic
Device Evaluation and Safety

510(k) K060570