Section 11 510(k) Device Summary

510(k) SUMMARY

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

The assigned 510(k) number is K021484.

Submitter	Canterbury Scientific Limited 21 Wroxton Terrace Christchurch New Zealand Phone and FAX (+643) 355 5598
Contact Person	Maurice Owen, Laboratory Manager, Canterbury Scientific Ltd.
Date of Preparation	03 May 2002
Device Name	Hemoglobin A1c Control
Classification	Class II, LCP
Equivalent Device	Lyphochek Diabetes Control Level 1 & 2, Bio-Rad Laboratories. (510(k) = K831478)
Description of Device	The Hemoglobin A1c Control contains both Normal and Abnormal level Controls. They are intended for use as a quality control material to monitor the precision of laboratory testing procedures for HbA1c quantitation. They are prepared from normal adult human blood The source blood is tested and found to be non-reactive for Hepatitis B surface antigen, Hepatitis C antibody, antibodies against human immunodeficiency virus (HIV) types 1 & 2, and Syphilis (RPR and TPHA). The Abnormal Level Control is prepared by controlled glycation of normal non-diabetic hemolysate. The controls are reconstituted with distilled water or a reconstitution solution comprising the biocide sodium azide (0.09%). The reconstitution volume is between 0.25 mL and 0.5 mL. The controls reconstitute in 15 minutes with occasional swirling, and are stored at 2° - 8°C.

Intended Use of Device

The Hemoglobin A1c Control is intended for use as a quality control material to monitor the precision of laboratory testing procedures for HbA1c quantitation.

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. The two levels of controls allow performance monitoring within the clinically important range.

The measurement of HbA1c is especially useful in insulin-dependent diabetic patients where blood glucose levels fluctuate widely and where the instantaneous blood glucose does not reflect the averaged situation. The formation of HbA1c occurs slowly (about 0.05%/day) and continuously during the 120-day lifetime of the red cell. Hence the measurement of HbA1c is useful to physicians as a long-term integral of blood glucose concentration and thus as a measure of the degree of control or self-management by the diabetic patient. The normal range for HbA1c is 4% - 6% of total hemoglobin. Each percentage point increase in HbA1c level corresponds to an increase in average blood glucose level of about 30 mg/dL or 1.7mmol/L. As a general rule HbA1c levels above 10% represent poor diabetic control, whereas values of about 7% are indicative of good control.

The controls are for in vitro diagnostic use only and should not be used past the expiry date. They are not intended to be used as standards or calibrants.

Comparison of Technological Characteristics with Predicate Device

	Hemoglobin A1c Control New Device	***Lyophochek Diabetes Control, Levels 1 and 2 Bio-Rad Laboratories***
510(k) Number		K831478
Type of Product	Quality Control Product	Quality Control Product
Description	Lyophilized Hemoglobin Control	Lyophilized Hemoglobin Control
Type of Vial and Cap	3.5mL clear borosilicate glass vial with plastic screw cap and phenolic moisture barrier liner.	10 mL amber glass serum vial with butyl rubber insert and aluminum crimp top.
Intended Use	As a quality control lysate to monitor the precision of laboratory procedures for measurement of HbA1c	As a quality control lysate to monitor the precision of laboratory procedures for measurement of HbA1c and HbA1
Contents of Vials	Human hemoglobins (HbA, HbA1c, HbF, HbA_2), Cryopreservative, broad spectrum antibiotic, stabilizers.	Human hemoglobins (HbA, HbA1c, HbF, HbA_2, HbS), preservatives, stabilizers
Serology Testing of Human Source Material	Non-reactive for: • Hepatitis B Surface Antigen • Antibody to Hepatitis C • Antibody to HIV-1 & HIV-2 • Syphilis (TPHA & RPR)	Non-reactive for: • Hepatitis B Surface Antigen • Antibody to Hepatitis C • Antibody to HIV-1 & HIV-2 Syphilis testing status not known
Number of Levels	2 (Normal and Abnormal)	2 (Level 1 [normal] and level 2 [Abnormal])
Storage	2°-8°C	2°-8°C
Stability of Lyophilized Product	3 years at 2° - 8°C	? 3 years at 2° - 8°C
Stability Reconstituted Control	13 weeks at 2°-8°C	7 days at 2° - 8°C
Reconstitution Volume	0.25 – 0.5mL	0.5mL
Moisture (Loss on Drying)	Less than 3%	Not known, but likely to be less than 3%
Target Value and acceptable range for Level 1 Composition (For the Bio-Rad product the target figures are not known, so a typical range (lot 33591) is given)	5.0% (4.5% - 6.0%)	Mean 5.1% - 5.6% (range 4.7% - 6.0%) for HPLC methods given in information sheet
Target Value and acceptable range for Level 2 Composition (For the Bio-Rad product the target figures are not known, so a typical range (lot 33592) is given)	10.5% (10.0% - 13.0%)	Mean 9.8% - 10.3% (range 9.0% - 11.3%) for HPLC methods given in information sheet
Methods Suitable for Controls	HPLC, latex immunoagglutination inhibition	HPLC, latex immunoagglutination inhibition

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
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Re: k021484
Trade/Device Name: Hemoglobin A1c Control
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Code: LCP
Dated: May 30, 2002
Received: June 3, 2002

Dear Dr. Owen:

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 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 Part 801); 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.

This letter will allow you to begin marketing your device as described in your 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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 10 Statement of Indications for Use

10.1 Device Name

Hemoglobin A1c Control

10.2 Indications for Use

The Hemoglobin A1c Control contains both Normal and Abnormal level Controls. They are intended for use as a quality control material to monitor the precision of laboratory testing procedures for HbA1c quantitation.

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K021784