K041635

AUG 16 2004

510(k) Summary for G5 I HbA_{1c} Test SYSTEM

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact	Owner/ Operator Provalis Diagnostics Limited Newtech Square Deeside Industrial Park Deeside Flintshire CH5 2NT UK
Contact Person:	Mrs Jan Barrack, Regulatory Affairs Manager
Telephone:	+44 1244 288888
Facsimile:	+44 1244 833441
Email:	JanBarrack@Provalis.com
USA contact person	Tom Tsakeris
Company	Devices and Diagnostics Consulting Group, Inc
Address:	16809 Briardale Road, Rockville, MD 20855 USA
Telephone:	301 330 2076
Facsimile:	301 330 2568
Email:	DDCGI@Comcast.net
Date Prepared	5th June 2004

2) Device name	Proprietary name: Common name: Classification:	G5 I HbA_{1c} Test Laboratory test for the detection of Glycated Haemoglobin in Human Whole Blood. ASSAY, GLYCOSYLATED HAEMOGLOBIN
3) Predicate Device	The G5 I HbA_{1c} test is substantially equivalent to other products in commercial distribution for similar use, including the Glycosal HbA_{1c} Test.	
4) Device Description	Instrument read, single use *in vitro* test for the quantitative determination of glycated haemoglobin (GHb) in diabetics.	
5) Intended use	The G5 I HbA_{1c} assay is an affinity chromatography method and is intended for the in-vitro quantitative determination of HbA_{1c} in capillary blood taken from a finger prick or whole blood in EDTA. The test is indicated for use by diabetics for monitoring the time averaged blood glucose levels of known diabetics as an indicator of overall glycaemic control. The G5 I HbA_{1c} assay is intended for use in a physicians/doctors office. The assay is not intended for use as a home use or for self-testing.	

510(k) Summary for G5 II HbA_{1c} Test

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

2) Submitter name, address, contact	Owner/ Operator Provalis Diagnostics Limited Newtech Square Deeside Industrial Park Deeside Flintshire CH5 2NT UK
Contact Person:	Mrs Jan Barrack, Regulatory Affairs Manager
Telephone:	+44 1244 288888
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Email:	DDCGI@Comcast.net
Date Prepared	5th June 2004

2) Device name	Proprietary name: Common name: Classification:	G5 II HbA_{1c} Test Prescription Home Use Test for the detection of Glycated Haemoglobin in Human Whole Blood. ASSAY, GLYCOSYLATED HAEMOGLOBIN
5) Predicate Device	The G5 II HbA_{1c} test is substantially equivalent to other products in commercial distribution for similar use, including the Glycosal II HbA_{1c} Test for prescription home use.	
6) Device Description	Instrument read, single use *in vitro* test for the quantitative determination of glycated haemoglobin (GHb) in diabetics.	
5) Intended use	The G5 II HbA_{1c} assay is an affinity chromatography method and is intended for the in-vitro quantitative determination of HbA_{1c} in capillary blood taken from a finger prick The test is indicated for use by diabetics for monitoring the time averaged blood glucose levels of known diabetics as an indicator of overall glycaemic control. The G5 II HbA_{1c} assay is intended for use as a prescription home use test.	

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Technological Similarities and Differences of the G5 I HbA1c and G5 II HbA1c tests to the Predicate Devices

Characteristic	**Candidate Device** G5 I and G5 II HbA_{1c} test	**Primary Predicate Device for G5 I** Glycosal™ HbA_{1c} test	**Primary Predicate Device for G5 II** Glycosal™ II HbA_{1c} test
Intended Use	Quantitative measurement of the percent of Glycated Hemoglobin.	Quantitative measurement of the percent of Glycated Hemoglobin.	Quantitative measurement of the percent of Glycated Hemoglobin.
Indications for Use	Used in the management and treatment of Diabetes, for monitoring long term glycemic control.	Used in the management and treatment of Diabetes, for monitoring long term glycemic control.	Used in the management and treatment of Diabetes, for monitoring long term glycemic control.
Risk to Patient	Not a critical analyte - reflects glucose monitoring over time	Not a critical analyte - reflects glucose monitoring over time	Not a critical analyte - reflects glucose monitoring over time
Detects	Glycated Hemoglobin (GHb)	Glycated Hemoglobin (GHb)	Glycated Hemoglobin (GHb)
Methodology	Rapid Affinity Chromatography test	Rapid Affinity Chromatography test	Rapid Affinity Chromatography test
Does the Device perform a Diagnostic Interpretation?	No	No	No
Quantitative Test?	Yes	Yes	Yes
Calibration	Not required by end-user; each instrument is factory calibrated	Not required by end-user; each instrument is factory calibrated	Not required by end-user; each instrument is factory calibrated
Total Test time	7 minutes	4 minutes	4 minutes
Procedural Steps	1. Add sample 2. Place device in instrument 3. Record result	1. Add sample 2. Incubate sample for 60 seconds. 3. Pour sample 4. Wash 5. Elute fraction 6. Record result	1. Add sample 2. Incubate sample for 60 seconds 3. Pour sample 4. Wash 5. Elute fraction 6. Record result
Visual Display	LCD readout	LCD readout	LCD readout
Testing Environment	Physicians office/Doctors Office (G5 I) Prescription Home Use (G5 II)	Physicians Office/Doctors Office	Prescription Home Use Patient Labelling

6) Performance Characteristics

Clinical Studies

Clinical trial carried out at Southport DGH, UK to evaluate a rapid blood test for the measurement of Glycated protein in subjects with type I and type II diabetes mellitus

The data from 74 patients demonstrated that the G5 HbA_{1c} assay is substantially equivalent to the Glycosal assay with a correlation coefficient of 0.96 for fresh finger prick and 0.97 for stored EDTA blood.

POL Studies (G5 I)

Evaluation of the G5 HbA_{1c} test using non-laboratory participants
Three separate Physician Office Laboratory (POL) studies were carried out. Each consisting of 5 standards run in triplicate and at least 20 blood samples (EDTA stored blood and/or fresh finger prick) run by a trained operator and an untrained operator. Each site produced acceptable data for accuracy and precision, with correlation coefficients of ≥ 0.95, accuracy within ± 10% and CV less than 4.6%.

Home Use – Consumer Study (G5 II)
This study took place at 3 separate sites in the USA and compared untrained subjects to trained subjects. The untrained subjects using only the supplied packaging achieved acceptable correlation to the trained operators.

Non Clinical Laboratory Studies

Assessing the linearity of the G5 HbA_{1c} assay
A study was conducted to prove the G5 HbA_{1c} is linear over the assay range. Results demonstrated that the assay is linear between 6 and 14% HbA_{1c}.

The effect of Haemoglobinopathies on the G5 HbA_{1c} assay
This validation is covered by reference WG John. Glycated haemoglobin analysis. Ann Clin Biochem 1997; 34: 17-31. Boronate methodology is not affected by HbS, HbC, HbF or by high levels of carbamylated haemoglobin in Uremic patients.

The Effect of Abnormal blood chemistries upon the accuracy of the G5 HbA_{1c} assay
The effect of abnormal blood chemistries, ***i.e.*** raised lipids and raised bilirubin upon the determination of $\%HbA_{1c}$ needed to be investigated. Triglycerides up to 4.0 mmol/L and Bilirubin up to 345µmol/L do not affect the test result.

The Effect of Interfering Drugs upon Accuracy of the G5 HbA_{1c} assay
The effect of the commonly prescribed pharmaceutical drugs (aspirin, paracetemol, caffeine and anti-histamine) upon the performance of the G5 HbA_{1c} test needed to be assessed. None of the listed compounds affected the HbA_{1c} test result.

Investigating the effect of labile HbA_{1c} on the G5 HbA_{1c} assay
This validation is covered by reference WG John. Glycated haemoglobin analysis. Ann Clin Biochem 1997; 34: 17-31. Boronate Methodology is not affected by Labile HbA_{1c}.

Investigating the analysis of variance of reproducibility of the G5 HbA_{1c} assay
A study was performed to investigate the analysis of variance of reproducibility of the G5 HbA_{1c} assay. Using a normal and an abnormal control, which were assayed in duplicate twice during each day over a period of 20 days, it was demonstrated that the variance was acceptable, with an overall CV precision of less than 5%.

Investigating the assay reproducibility (Inter batch variation) of the G5 HbA_{1c} assay
A study was performed to determine the intra and inter batch variation of the G5 HbA_{1c} assay. Using 3 $\%HbA_{1c}$ standards on 3 batches of G5 devices it was demonstrated that the G5 assay was acceptable in terms of repeatability and reproducibility with assay %CV's of less than 5%.

Investigation into the use of stored blood for the G5 HbA_{1c} assay
The effect of running G5 assays with stored whole blood (EDTA) needed to be examined to assess the use of stored whole blood as an alternative to fresh finger pricks. It was demonstrated that the assay can be run acceptably with fresh finger prick, EDTA blood for up to 4 days after collection when the blood is stored at 2-8°C.

Investigating the effect of Total Haemoglobin and Haematocrit on the G5 HbA_{1c} assay
The effect of the variation in total haemoglobin and haematocrit on $\%HbA_{1c}$ needed to be established. Results demonstrated that the assay performs acceptably within a haemoglobin range of 11-18g/dl and a haematocrit range of 35% to 55%.

G5 HbA_{1c} test cartridge stability
The stability of the G5 HbA_{1c} assay needed to be established. Results demonstrated that the assay is stable for at least 12 months at 2-8°C.

Assessing the time required to equilibrate the G5 device to room temperature from 2-8°C

The minimum time required to equilibrate the G5 devices to room temperature before use needed to be established. The results demonstrated that the minimum time required for equilibration is 2 hours.

Assessing the acceptable time a device can be left after sample addition prior to insertion into the G5 reader

The acceptable time a device can be left after sample addition prior to insertion into the G5 reader needed to be assessed. The results demonstrated that the device needed to be inserted immediately after sample addition

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G5 HbA_{1c} Quality Control Kit

Provalis use commercially available controls from Aalto scientific Ltd; Glycohemoglobin controls normal and abnormal. 510(k) K952720.

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7) Conclusion: These performance characteristics clearly indicate substantial equivalence of the G5 I HbA_{1c} test with the Glycosal HbA_{1c} test and the G5 II HbA_{1c} test with the Glycosal II HbA_{1c} test and provides a comparative accuracy to other cleared and commonly accepted methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 16 2004

Provalis Diagnostics Ltd.
c/o Mr. Thomas M. Tsakeris
Devices and Diagnostics Consulting Group, Inc.
16809 Briardale Rd.
Rockville, MD 20855

Re: k041635
Trade/Device Name: G5 II HbA_{1c} Test System
G5 I HbA_{1c} Test System
Regulation Number: 21 CFR 864.7470
Regulation Name: Glycosylated hemoglobin assay
Regulatory Class: Class II
Product Code: LCP, GGM
Dated: June 16, 2004
Received: June 16, 2004

Dear Mr. Tsakeris:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS, DVM.

Jean M. Cooper, MS, D.V.M.
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): K041635

Device Name: G5 II HbA_{1c} Test System

Indications For Use: Indications for Use: The G5 II HbA1c Test System is intended for testing blood taken from a fingerprick.

G5 II HbA1c Test System shows how good glucose control has been over a two to three month period.

The G5 II HbA1c Test System consists of the HbA1c test cartridge, the G5 Instrument, the G5 System Check Cartridge and the G5 HbA1c Quality Controls.

The G5 II HbA1c Test System is intended for prescription home use.

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) K041635

Indications for Use

510(k) Number (if known): K041635

Device Name: G5 I HbA_{1c} Test System

Indications For Use: Indications for Use: The G5 I HbA1c Test System is an affinity chromatography method and is intended for the in vitro quantitative determination of HbA1c in capillary blood taken from a fingerprick or whole blood in EDTA.

G5 I HbA1c Test System is indicated for monitoring the time averaged blood glucose levels of known diabetics, for professional use as an indicator of overall Glycaemic control.

The G5 I HbA1c Test System consists of the HbA1c test cartridge, the G5 Instrument, the G5 System Check Cartridge and the G5 HbA1c Quality Controls.

The G5 I HbA1c Test System is intended for use in a physicians/ doctors office.

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

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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

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