# Section 5 : 510(k) Summary

MAY 19 2011

**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.

The assigned 510(k) number is : **K100547**


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**Date of Preparation** February 8th, 2010

**Device names**

REAGENT :

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|---|---|
| Trade/proprietary Name: | **ELITech Clinical Systems HbA1c** |
| Common or Usual Name: | Glycosylated Hemoglobin "**HbA1c**" |
| Device Class | Class II |
| Classification name | Assay, Glycosylated Hemoglobin (Sec.864.7470) |
| Product code | LCP; Assay, Glycosylated Hemoglobin |

**Predicate device** Hemoglobin A1c Reagent Set (K031539)

**Device description** The device for this submission is available as a kit only. It consists of 3 reagents.
*Reagent R1* contains suspended latex particles in a buffer with stabilizers and sodium azide.
*Reagent R2a and Reagent R2b* are mixed to prepare a working reagent, Reagent 2. This mixture contains Mouse anti-human HbA1c monoclonal antibody and Goat anti-mouse IgG polyclonal antibody in a buffer containing stabilizers and sodium azide.
*Reagent R3,* a hemolysis reagent, is an aqueous solution containing sodium azide.

**Intended Use** ELITech Clinical Systems HbA1c is intended for use in the quantitative *in vitro* diagnostic determination of hemoglobin A1c (HbA1c) in human whole blood on Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings.

**Indication for use** HbA1c measurements are used for the monitoring of long term blood glucose control in diabetic patients.

**Comparison to Predicate device**

| | **ELITech Clinical Systems Device** (HbA1c) | **Predicate device** (Pointe Scientific Hemoglobin A1c Reagent Set) |
|---|---|---|
| Intended use | ELITech Clinical Systems HbA1c is intended for use in the quantitative *in.vitro* diagnostic determination of hemoglobin A1c (HbA1c) in human whole blood on Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings. | For the quantitative determination of hemoglobin A1c (HbA1c) in human blood. For *in vitro* diagnostic use only. |
| Indication for Use | HbA1c measurements are used for the monitoring of long term blood glucose control in diabetic patients. | The determination of hemoglobin A1c is most commonly performed for the evaluation of glycemic control in diabetes. Hemoglobin A1c values provide an indication of glucose levels over the preceding 4-8 weeks. A higher hemoglobin A1c value indicates poorer glycemic control. |
| Assay protocol | Immuno-turbidimetry enhanced by latex particles using a two-reagent reaction sequence. | Same. |
| Composition | Reagent R1 :<br>Suspended latex particles 0.13%; Buffer, stabilizers ; sodium azide < 0.1%<br><br>Working Reagent R2 (R2a+R2b):<br>Mouse anti-human HbA1c monoclonal antibody 0.05 mg/mL; Goat anti-mouse IgG polyclonal antibody 0.08 mg/dL; Buffer, stabilizers ; sodium azide < 0.1%<br><br>Reagent R3 (Hemolysis reagent)<br>Aqueous solution; sodium azide < 0.1 % | Reagent R1 :<br>Latex particles (uncoated) 0.13%; Buffer, stabilizers ; sodium azide < 0.1%<br><br>Reagent R2 (when combined):<br>Mouse anti-human HbA1c monoclonal antibody 0.05 mg/mL; Goat anti-mouse IgG polyclonal antibody 0.08 mg/dL; Buffer, stabilizers ; sodium azide < 0.1%<br><br>Hemolysis reagent<br>Water and stabilizer. |
| Appearance of reagents | Liquid form.<br>Reagents R1 and R3 are ready to use.<br>Reagent R2 is a working reagent that must be prepared by mixing the content of Reagent R2b in the vial R2a. | Reagent R1 and hemolysis reagent are supplied as ready to use liquids.<br>Reagent R2 is prepared by pouring the entire contents of the R2b vial into the R2a vial. |
| Traceability/Standardization | Values are defined in the reference NGSP values and traceable to the IFCC reference method. | Against IFCC and NGSP traceable reference materials |
| Sample type | Whole blood collected on EDTA | Venous blood with EDTA |
| Reagent storage | To store at 2-8 °C and protected from light. The reagents are | To store at 2-8°C. The reagents are stable until the expiry date |

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| | stable until the expiry date stated on the label | stated on the label |
| Expected values | Non-diabetics : 4.0 -6.0 % | < 6 % for a non-diabetics<br>< 7 % for glycemic control of a person with diabetes. |
| Instrument | SELECTRA JUNIOR | Pointe Scientific Hitachi instruments (model 717 or 917) |
| Measuring range | 2.5 to 16 % | 2 to 16 % |
| Limit of Blank (LoB) | 0.6 % | |
| Limit of Detection (LoD) | 0.7% | |
| Precision | **Within run**<br>Level 4.4 % CV= 1.1 %<br>Level 6.7 % CV= 0.9 %<br>Level 9.5 % CV= 1.0 %<br><br>**Total**<br>Level 4.4 % CV= 2.3 %<br>Level 6.7 % CV= 1.9 %<br>Level 9.5 % CV= 2.9 % | **Within run**<br>Level 5.48 % CV= 1.43 %<br>Level 10.28 % CV= 1.72 %<br><br>**Day to Day**<br>Level 5.48 % CV= 2.77 %<br>Level 10.28 % CV= 2.68 % |
| Method comparison | y=0.926x + 0.1 %<br>r= 0.984 | y=1.050x – 0.481 %<br>r= 0.988 |
| Limitations | No significant interference for the following components:<br><br>- **Unconjugated bilirubin** (up to 30 mg/dL)<br>- **Conjugated bilirubin** (up to 29.5 mg/dL)<br>- **Triglycerides** (up to 2000 mg/dL)<br>- **Acetylsalicylic acid** (up to 200 mg/dL)<br><br>- **Rhumatoid factor** (up to 1000 IU/mL)<br>- **Ascorbic acid** (up to 20 mg/dL)<br><br>- Interference due to **Vitamin E** has not been assessed.<br><br>Hemoglobin variants:<br>- **HbC, HbS, HbD, HbE and HbA2:** No significant interference.<br>- **High concentration of HbF** lead to a underestimation of HbA1c.<br><br>Chemically modified Hemoglobin:<br>- ***Carbamylated hemoglobin***: No significant interference up to 10 mmol/L of added sodium cyanate.<br>- ***Acetylated hemoglobin***: No significant interference up to 10 | No significant interference for the following components<br><br>**Bilirubin** to 50 mg/dL<br>**Triglycerides** to 2000 mg/dL<br>**Carbamylated hemoglobin** to 7.5 mmol/L<br>**Acetylated hemoglobin** to 5.0 mmol/L<br>**Hemoglobin variants** : HbA2, HbC, HbS, HbE<br><br>Elevated levels of HbF may lead to an underestimation of HbA1c. |

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| | mmol/L of added aspirin.<br>- **Labile HbA1c**: No significant interference up to 1000 mg/dL of added glucose.<br>- It has been reported that results may be unreliable with patients who suffer from alcoholism (formation of acetaldehyde hemoglobin) | |

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| **Conclusion** | The performance data and other information conclude that the safety and effectiveness of the device is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device. |

**Device names**

CALIBRATOR :

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| Trade/proprietary Name: | **ELITech Clinical Systems HbA1c Calibrator Set** |
| Common or Usual Name: | Calibrator for Glycosylated Hemoglobin , "**HbA1c Calibrator Set**" |
| Device Class | Class II |
| Classification name | Calibrator for Hemoglobin or Hematocrit measurement (21 CFR Sec.864.8165) |
| Product code | JIT - Calibrator for Glycosylated Hemoglobin |

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| **Predicate device** | Hemoglobin A1c calibrator Set (K031539) |

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| **Device description** | The device for this submission is available as kit only. It consists of 4 different levels of calibrator at 0.5 mL volume.<br>Each level consists of lyophilized hemolysates prepared from human erythrocytes.<br>HbA1c CALIBRATOR SET is prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods. |

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| **Intended Use** | ELITech Clinical Systems HbA1c CALIBRATOR SET is a calibrator with 4 different levels of values for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems HbA1c on Vital Scientific Selectra/Flexor analyzers as specified in the instructions for use. |

**Comparison to Predicate device**

| | **ELITech Clinical Systems Device** (HbA1c CALIBRATOR SET) | **Predicate Device** (Pointe Scientific Hemoglobin A1c Calibrator Set) |
|---|---|---|
| Intended use | ELITech Clinical Systems HbA1c CALIBRATOR SET is a calibrator with 4 different levels of values for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems HbA1c on Vital Scientific Selectra/Flexor analyzers as specified in the instructions for use. | For the purpose of calibrating results in the quantitative determination of human hemoglobin A1c (HbA1c) in blood by automated immunoassay. For *in vitro* diagnostic use only. |
| Format | Lyophilized hemolysates from human erythrocytes. | Hemolysate prepared from packed human erythrocytes. |
| Levels | Four (4) levels | Four (4) levels |
| Handling | Reconstitute each calibrator using 0.5 mL of deionized water. Gently mix for 10 minutes or until all material has dissolved. Each Control should be hemolysis before use | Same |
| Stability | Prior to reconstitution : To store at 2-8 °C and protected from light until the expiry date<br><br>After reconstitution : Calibrators are stable 30 days when stored at 2-8 °C<br>- After opening, the vials should be kept correctly and tightly capped to prevent contamination and evaporation | Same |

**Conclusion** The performance data and other information conclude that the safety and effectiveness of the device is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to his respective predicate device.

**Device names**

CONTROLS:

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| Trade/proprietary Name: | **ELITech Clinical Systems HbA1c CONTROL L + H** |
| Common or Usual Name: | Single (Specified) analyte control, Assayed, "**HbA1c CONTROL L + H**" |
| Device Class | Class I |
| Classification name | Quality control material (assayed and unassayed). (Sec.862.1660) |
| Product code | JJX- Single (specified) analyte controls (assayed and unassayed) |

**Predicate device** Hemoglobin A1c Control Set (K031539)

**Device description** ELITech Clinical Systems HbA1c Control L + H is a two level quality control products consisting of lyophilized hemolysates prepared from human erythrocytes containing constituents at desired levels.
HbA1c CONTROL L+ H is prepared exclusively from the blood of donors tested individually and found to be negative for HbsAg and to antibodies to HCV and HIV according to FDA-approved methods.

**Intended Use** ELITech Clinical Systems HbA1c CONTROL L+ H is a quality control with 2 levels of values (Low and High values) for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems HbA1c on Vital Scientific Selectra/Flexor analyzers as specified in the instructions for use.

**Comparison to Predicate device**

| | **ELITech Clinical Systems Device** (HbA1c CONTROL L+H ) | **Predicate Device** (Pointe Scientific Hemoglobin A1c Control Set) |
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| Intended use | ELITech Clinical Systems HbA1c CONTROL L+ H is a quality control with 2 levels of values (Low and High values) for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems HbA1c on Vital Scientific Selectra/Flexor | For the purpose of monitoring accuracy and precision in the quantitative determination of human hemoglobin A1c (HbA1c) in blood by automated immunoassay. For *in vitro* diagnostic use only. |

| | **ELITech Clinical Systems Device** (HbA1c CONTROL L+H ) | **Predicate Device** (Pointe Scientific Hemoglobin A1c Control Set) |
|---|---|---|
| | analyzers as specified in the instructions for use. | |
| Format | Lyophilized hemolysates from human erythrocytes. | Hemolysate prepared from packed human erythrocytes. |
| Levels | Two (2) levels | Two (2) levels |
| Handling | Reconstitute each control using 0.5 mL of deionized water, Gently mix for 10 minutes or until all material has dissolved. Each Control should be hemolysis before use | Same |
| Stability | Prior to reconstitution : To store at 2-8 °C and protected from light until the expiry date<br><br>After reconstitution : Controls are stable 30 days when stored at 2-8 °C<br>- After opening, the vials should be kept correctly and tightly capped to prevent contamination and evaporation | Same |

**Conclusion** The performance data and other information conclude that the safety and effectiveness of the device is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to his respective predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAY 19 2011

SEPPIM S.A.S
c/o Debra Hutson
ELITechGroup Epoch Biosciences
21720 23rd Dr. SE, Suite 150
Bothell, Washington 98021

Re: k100547
Trade Name: ELITech Clinical Systems HbA1c Reagent, ELITech Clinical Systems HbA1c Calibrator Set, ELITech Clinical Systems HbA1c Control L+H
Regulation Number: 21CFR 864.7470
Regulation Name: Glycosylated Hemoglobin Assay
Regulatory Class: Class II
Product Codes: LCP, JIT, JJX
Dated: April 18, 2011
Received: April 19, 2011

Dear Ms Hutson:

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); 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 Parts 801 and 809), 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 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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, 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 Form

510(k) Number (if known): K100547

Device Name: ELITech Clinical Systems HbA1c

Indications for Use:

ELITech Clinical Systems HbA1c is intended for use in the quantitative *in vitro* diagnostic determination of hemoglobin A1c (HbA1c) in human whole blood on Vital Scientific Selectra/Flexor analyzers.It is not intended for use in Point of Care settings.

HbA1c measurements are used for the monitoring of long term blood glucose control in diabetic patients.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

510(k) K100547

# Indications for Use Form

510(k) Number (if known): k100547

Device Name: ELITech Clinical Systems HbA1c calibrator set

Indications for Use:

ELITech Clinical Systems HbA1c Calibrator set is a calibrator with 4 different levels of values for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems HbA1c on Vital Scientific Selectra/Flexor analyzers as specified in the instructions for use.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

510(k) k100547

# Indications for Use Form

510(k) Number (if known): K100547

Device Name: ELITech Clinical Systems HbA1c Control L+ H

Indications for Use:

ELITech Clinical Systems HbA1c Control L+H is a quality control with 2 levels of values (Low and High values) for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems HbA1c on Vital Scientific Selectra/Flexor analyzers as specified in the instructions for use.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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

510(k) K100547