SECTION 5 - 510(k) Summary
ELITech Clinical Systems GLUCOSE PAP SL reagent

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: K100525

Submitter: SEPPIM S.A.S.
Address: Zone Industrielle, 61500 SEES, FRANCE
Phone number: +33 (0)2 33 81 21 00
Fax number: +33 (0)2 33 28 77 51
Contact: Valérie GOURDON (Email: v.gourdon@elitechgroup.com)
Date of Preparation: Monday, February 15th 2010

Device names

<table>
<thead>
<tr>
<th>REAGENT</th>
<th>Trade/proprietary Name: ELITech Clinical Systems GLUCOSE PAP SL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common or Usual Name: Glucose, “GLUCOSE PAP SL”</td>
<td></td>
</tr>
<tr>
<td>Device Class: Class II</td>
<td></td>
</tr>
<tr>
<td>Classification name: Glucose test system (Sec.862.1345)</td>
<td></td>
</tr>
<tr>
<td>Product code: CGA – Glucose Oxidase, Glucose</td>
<td></td>
</tr>
</tbody>
</table>

Predicate device: ABX PENTRA GLUCOSE PAP CP (K052007)

Device description
The device for this submission is available as kit only. It consists of 1 reagent, “R.”
Reagent R consists of Phosphate buffer (pH 7.4), Phenol, 4-Aminoantipyrine (4-AAP), Glucose oxidase (Aspergillus sp.), Peroxidase (horseradish) and sodium azide.

Intended Use
ELITech Clinical Systems GLUCOSE PAP SL is intended for use with ELITech Clinical Systems ELICAL 2 and ELITech Clinical Systems ELITROL I and ELITROL II on Vital Scientific Selectra/Flexor analyzers for the quantitative in vitro diagnostic determination of glucose in human serum and plasma. It is not intended for use in Point of Care settings.

Indication(s) for Use
ELITech Clinical Systems GLUCOSE PAP SL is intended to measure glucose in human serum and plasma. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.
**Comparison to Predicate device**

<table>
<thead>
<tr>
<th></th>
<th>ELITech Clinical Systems Device</th>
<th>Predicate device (ABX PENTRA GLUCOSE PAP CP)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Intended use</strong></td>
<td>Intended for use with ELITech</td>
<td>For in vitro diagnostic use in the</td>
</tr>
<tr>
<td></td>
<td>Clinical Systems ELICIAL 2 and</td>
<td>quantitative determination of glucose</td>
</tr>
<tr>
<td></td>
<td>ELITech Clinical Systems ELIT-</td>
<td>in serum and plasma.</td>
</tr>
<tr>
<td></td>
<td>TROL I and ELITROL II on Vital</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Scientific Selectra/Flexor analyzers for the quantitative in vitro diagnostic determination of glucose in human serum and plasma. It is not intended for use in Point of Care settings.</td>
<td></td>
</tr>
<tr>
<td><strong>Indication(s) for Use</strong></td>
<td>Intended to measure glucose in human serum and plasma. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.</td>
<td>Intended to measure glucose in human serum and plasma. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.</td>
</tr>
<tr>
<td><strong>Assay protocol</strong></td>
<td>Enzymatic method using glucose oxidase coupled with peroxidase (Trinder method).</td>
<td>Enzymatic method using glucose oxidase coupled with peroxidase (Trinder method).</td>
</tr>
<tr>
<td><strong>Composition</strong></td>
<td>Reagent R: Phosphate buffer; pH 7.4 13.8 mmol/L; Phenol 10 mmol/L; 4-Aminoantipyrine 0.3 mmol/L; Glucose oxidase ≥ 10 000 U/L; Peroxidase ≥ 700 U/L; Sodium azide &lt; 0.1%;</td>
<td>Reagent: Phosphate buffer; pH 7.4 13.8 mmol/L; Phenol 10 mmol/L; 4-Aminoantipyrine 0.3 mmol/L; Glucose oxidase ≥ 10 000 U/L; Peroxidase ≥ 700 U/L; Sodium azide &lt; 0.1%;</td>
</tr>
<tr>
<td><strong>Appearance of reagent</strong></td>
<td>Liquid form, ready to use</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Sample type</strong></td>
<td>Serum, Plasma</td>
<td>Serum, Plasma</td>
</tr>
<tr>
<td><strong>Reagent storage</strong></td>
<td>Store at 2-8 °C and protected from light. The reagent is stable until the expiry date stated on the label.</td>
<td>Reagents, in unopened cassette, are stable up to expiry date on the label if stored at 2-8 °C.</td>
</tr>
<tr>
<td><strong>Expected values</strong></td>
<td>Serum, plasma 74 – 106 mg/dL</td>
<td>Serum, plasma 74 – 106 mg/dL</td>
</tr>
<tr>
<td><strong>Instrument</strong></td>
<td>SELECTRA JUNIOR</td>
<td>ABX PENTRA 400</td>
</tr>
<tr>
<td><strong>Measuring range</strong></td>
<td>20.0 to 400.0 mg/dL Run: 800.0 mg/dL</td>
<td>1.8 to 432 mg/dL Automatic post-dilution: 1296 mg/dL</td>
</tr>
<tr>
<td><strong>Detection</strong></td>
<td>0.5 mg/dL</td>
<td>1.8 mg/dL</td>
</tr>
<tr>
<td><strong>Precision</strong></td>
<td><strong>Within run</strong></td>
<td><strong>Within run</strong></td>
</tr>
<tr>
<td></td>
<td>Level 36.5 mg/dL CV=1.6%</td>
<td>Level 89.36 mg/dL CV=0.41%</td>
</tr>
<tr>
<td></td>
<td>Level 107.4 mg/dL CV=1.4%</td>
<td>Level 230.53 mg/dL CV=0.40%</td>
</tr>
<tr>
<td></td>
<td>Level 301.5 mg/dL CV=1.0%</td>
<td>Level 42.76 mg/dL CV=0.62%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Level 111.47 mg/dL CV=0.30%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Level 296.22 mg/dL CV=0.49%</td>
</tr>
<tr>
<td></td>
<td>ELITech Clinical Systems Device</td>
<td>Predicate device</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------------------</td>
<td>-------------------</td>
</tr>
<tr>
<td></td>
<td>GLUCOSE PAP SL</td>
<td>(ABX PENTRA GLUCOSE PAP CP)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>36.5 mg/dL CV=2.9%</td>
<td></td>
<td>Level 90.20 mg/dL CV=1.23%</td>
</tr>
<tr>
<td>107.4 mg/dL CV=2.5%</td>
<td></td>
<td>Level 235.44 mg/dL CV=1.12%</td>
</tr>
<tr>
<td>301.5 mg/dL CV=2.1%</td>
<td></td>
<td>Level 107.18 mg/dL CV=1.44%</td>
</tr>
<tr>
<td>Level</td>
<td></td>
<td>Level 298.97 mg/dL CV=1.05%</td>
</tr>
</tbody>
</table>

Method comparison

\[
y = 0.953x + 3.05 \text{ mg/dL} \\
\text{range: } 17.9 \text{ to } 417.2 \text{ mg/dL}
\]

\[
y = 0.98x + 0.72 \text{ mg/dL} \\
\text{range: } 0.98 \text{ to } 0.9974
\]

**Limitations**

- **Hemoglobin**: Positive bias from 250 mg/dL on low human serum. No significant interference up to 500 mg/dL on medium human serum.
- **Triglycerides**: Positive bias from 814 mg/dL.
- **Unconjugated bilirubin**: Positive bias from 15 mg/dL on low human serum. Negative bias from 18 mg/dL on medium human serum.
- **Conjugated bilirubin**: Negative bias from 8 mg/dL on low human serum and from 18 mg/dL on medium human serum.
- **Ascorbic acid**: Negative bias from 2 mg/dL on low human serum and from 12 mg/dL on medium human serum.
- **Uric acid**: Negative bias from 19 mg/dL on low human serum. No significant interference up to 24 mg/dL on medium human serum.
- **Methyldopa**: Negative bias from 0.9 mg/dL on low human serum. No significant interference up to 1 mg/dL on medium human serum.
- **Hemoglobin**: No significant influence is observed up to 460 mg/dL.
- **Triglycerides**: No significant influence is observed up to 613 mg/dL.
- **Total bilirubin**: No significant influence is observed up to 8.19 mg/dL.
- **Direct bilirubin**: No significant influence is observed up to 5.63 mg/dL.

**Calibration Frequency**

- 28 days
- 11 days

**On board stability**

- Refrigerated area: 28 days
- Refrigerated area: 83 days

**Calibrator**

- Recommended calibration material (not included): ELITech Clinical Systems Elical 2
- Recommended calibration material (not included): ABX Pentra Multical

**Controls**

- Recommended quality control material (not included): ELITech Clinical Systems Elitrol I (Normal control)
- Recommended quality control material (not included): ABX Pentra N Control (Normal control)
- ELITech Clinical Systems Elitrol II (Pathologic control)
- ABX Pentra P Control (Pathologic control)

**Conclusion**

The performance data and other information demonstrate that the safety and effectiveness of this device versus the predicate device is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its predicate device.
SECTION 5 - 510(k) Summary - ELITech Clinical Systems ELICAL 2

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: K100525

Submitter
SEPPIM S.A.S.
Address
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Fax number
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Contact
Valérie GOURDON (Email: v.gourdon@elitechgroup.com)
Date of Preparation
Monday, February 15th 2010

Device names

REAGENT:
Trade/proprietary Name: ELITech Clinical Systems ELICAL 2
Common or Usual Name: Calibrator, multi-analyte mixture, “ELICAL 2”
Device Class
Class II
Classification name
Calibrator (21 CFR 862.1150)
Product code
JIX- Calibrator, multi-analyte mixture

Predicate device
Roche Diagnostics Calibrator for Automated Systems (C.f.a.s) (K033501)

Device description
ELITech Clinical Systems ELICAL 2 is a lyophilized calibrator based on human serum containing constituents to ensure optimal calibration.
ELICAL 2 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 or methods in compliance with the European Directive 98/79/EC, Annex II, List A.

Intended Use
### Comparison to Predicate device

<table>
<thead>
<tr>
<th></th>
<th>ELITech Clinical Systems Device (ELICAL 2)</th>
<th>Predicate device (Roche Calibrator f.a.s.)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Format</strong></td>
<td>Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels</td>
<td>Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels</td>
</tr>
<tr>
<td><strong>Level</strong></td>
<td>Single level</td>
<td>Single level</td>
</tr>
<tr>
<td><strong>Handling</strong></td>
<td>Carefully open the vial, avoiding the loss of lyophilate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the vial and dissolve the contents completely by occasional gentle swirling within 30 minutes avoiding the formation of foam.</td>
<td>Carefully open one bottle, avoiding the loss of lyophilate, and pipette in exactly 3 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.</td>
</tr>
<tr>
<td><strong>Traceability</strong></td>
<td>Traceability information is given in the value sheet included in the box.</td>
<td>Traceability of the target value is given in the respective instruction for use of the system reagents.</td>
</tr>
<tr>
<td><strong>Stability</strong></td>
<td>Lyophilized: To store at 2-8°C and protected from light until the expiry date. After reconstitution, the stabilities are: - 8 hours between 15-25 °C. - 2 days between 2-8 °C. - 4 weeks between -25 and -15 °C (when frozen once)</td>
<td>Lyophilized: Stable at 2-8°C up to expiration date. After reconstitution, the stabilities* are: - 8 hours at 15-25 °C. - 2 days at 2-8 °C. - 4 weeks at (-25)-(-15) °C (when frozen once)</td>
</tr>
</tbody>
</table>

*Exception for bilirubin total & direct as noted in package insert

### Elical 2 assigned values are the following ones:

<table>
<thead>
<tr>
<th>Components</th>
<th>Under review</th>
<th>Included in this submission</th>
<th>Cleared</th>
</tr>
</thead>
<tbody>
<tr>
<td>AST-GOT</td>
<td></td>
<td>X</td>
<td>K093883</td>
</tr>
<tr>
<td>Glucose</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Phosphorus</td>
<td>K100263</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Protein</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Urea</td>
<td>K100263</td>
<td></td>
<td></td>
</tr>
<tr>
<td>BUN</td>
<td>K100263</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Conclusion

The performance data and other information demonstrate that the safety and effectiveness of this device versus the predicate device is not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.
SECTION 5 - 510(k) Summary - ELITech Clinical Systems ELITROL I and ELITROL II

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: K100525

Submitter

SEPPIM S.A.S.

Address

Zone Industrielle, 61500 SEES, FRANCE

Phone number

+33 (0)2 33 81 21 00

Fax number

+33 (0)2 33 28 77 51

Contact

Valérie GOURDON (Email: v.gourdon@elitechgroup.com)

Date of Preparation

Monday, February 15th 2010

Device names

CONTROLS:

Trade/proprietary Name: ELITech Clinical Systems ELITROL I and ELITROL II
Common or Usual Name: Multi-analyte controls – all kinds, "ELITROL I" - "ELITROL II"
Device Class: Class I
Classification name: Quality control material (assayed and unassayed). (21 CFR 862.1660)
Product code: JJX- Multi-analyte controls – all kinds

Predicate device

Roche Diagnostics Precinorm U (K041227)
Roche Diagnostics Precipath U (K041227)

Device description

ELITech Clinical Systems ELITROL I and ELITROL II are two level quality control products consisting of lyophilized human serum containing constituents at desired levels.

Elitrol I and Elitrol II are 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 or methods in compliance with the European Directive 98/79/EC, Annex II, List A.

Intended Use


### Comparison to Predicate device

<table>
<thead>
<tr>
<th></th>
<th>ELITech Clinical Systems Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Format</strong></td>
<td>Lyophilized human sera with constituents added as required to obtain desired components levels</td>
<td>Lyophilized human sera with constituents added as required to obtain desired components levels</td>
</tr>
<tr>
<td><strong>Levels</strong></td>
<td>Two levels</td>
<td>Two levels</td>
</tr>
<tr>
<td><strong>Handling</strong></td>
<td>Carefully open the vial, avoiding the loss of lyophilate, and pipette in exactly 5 mL of distilled/deionized water. Carefully close the vial and dissolve the contents completely by occasional gentle swirling within 30 minutes avoiding the formation of foam.</td>
<td>Carefully open the bottle, avoiding the loss of lyophilate, and pipette in exactly 5 mL of distilled/deionized water. Carefully close the bottle and dissolve the contents completely by occasional gentle swirling within 30 minutes. Avoid the formation of foam.</td>
</tr>
<tr>
<td><strong>Stability</strong></td>
<td>Lyophilized: To store at 2-8°C and protected from light until the expiry date. After reconstitution, the stabilities are: - 12 hours between 15-25 °C. - 5 days between 2-8 °C. - 4 weeks between -25 and -15 °C (when frozen once)</td>
<td>Lyophilized: Stable at 2-8°C up to expiration date. After reconstitution, the stabilities* are: - 12 hours at 15-25 °C. - 5 days at 2-8 °C. - 4 weeks at (-25)°(-15) °C (when frozen once). *Exception for bilirubin total &amp; direct as noted in package insert</td>
</tr>
</tbody>
</table>

Elitol I & Elitol II assigned values are the following ones:

<table>
<thead>
<tr>
<th>Components</th>
<th>Under review</th>
<th>Included in this submission</th>
<th>Cleared</th>
</tr>
</thead>
<tbody>
<tr>
<td>AST-GOT</td>
<td></td>
<td></td>
<td>K093883</td>
</tr>
<tr>
<td>Glucose</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Phosphorus</td>
<td>K100263</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Total Protein | X
---|---
Urea | K100263
BUN | K100263
Uric acid | K100263
Cholesterol | K102993
Triglycerides | K102993

Conclusion

The performance data and other information demonstrate that the safety and effectiveness of these devices versus the predicate devices are not compromised, and that it met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.
Seppim S.A.S.
c/o Debra K. Hutson
ELITechGroup Epoch Biosciences
21720 23rd Dr. SE, Suite 150
Bothell, Washington 98021

Re: k100525
Trade Name: ELITech Clinical Systems Glucose PAP SL, ELITech Clinical Systems ELICAL 2, ELITech Clinical Systems ELITROL 1 and ELITROL 2
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: CGA, JIX, J1X
Dated: December 13, 2010
Received: December 15, 2010

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 \textit{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,

\begin{center}
\textit{C.J.}  \\
\textit{Courtney Harper, Ph.D.}  \\
\textit{Director}  \\
\textit{Division of Chemistry and Toxicology}  \\
\textit{Office of \textit{In Vitro} Diagnostic Device Evaluation and Safety}  \\
\textit{Center for Devices and Radiological Health}
\end{center}

Enclosure
Indications for Use Form

510(k) Number (if known): K100525

Device Name: ELITech Clinical Systems GLUCOSE PAP SL

Indications for Use:

ELITech Clinical Systems GLUCOSE PAP SL is intended for use with ELITech Clinical Systems ELICAL 2 and ELITech Clinical Systems ELITROL I and ELITROL II for the quantitative in vitro diagnostic determination of glucose in human serum and plasma on Vital Scientific Selectra/Flexor analyzers. It is not intended for use in Point of Care settings.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

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

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

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

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

510(k) K100525
Indications for Use Form

510(k) Number (if known): K100525

Device Name: ELITech Clinical Systems ELICAL 2

Indications for Use:


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

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

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

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

510(k) K100525
Indications for Use Form

510(k) Number (if known): _K100525_______

Device Name: __ELITech Clinical Systems ELITROL 1 and ELITROL 2__

Indications for Use:


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

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

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

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

510(k) _K100525__

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