SECTION 8 - 510(k) Summary

AUG 3 0 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: K112029

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Date of Preparation July 14, 2011

Device names

CALIBRATOR

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

ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for in vitro diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers

Comparison to Predicate device

	ELITech Clinical Systems Device (ELICAL 2)	Predicate device (Roche Calibrator f.a.s. K033501)
Intended use	ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.	For *in vitro* diagnostic use in the calibration of quantitative Roche methods on Roche clinical chemistry analysers as specified in the value sheets.
Format	Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels	Lyophilized calibrator based on human serum with constituents added as required to obtain desired components levels

	ELITech Clinical Systems Device (ELICAL 2)	Predicate device (Roche Calibrator f.a.s. K033501)
Level	Single level	Single level
Handling	Carefully open the vial, avoiding the loss of lyophilizate, 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.	Carefully open one bottle, avoiding the loss of lyophilizate, 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.
Traceability	Traceability information is given in the value sheet included in the box.	Traceability of the target value is given in the respective instruction for use of the system reagents.
Stability	Lyophilized: To store at 2-8°C and protected from light until the expiry date *After reconstitution, the stabilities are :* Between 15-25 °C : 8 hours Between 2-8 °C : 2 days Between (-25)-(-15) °C : 4 weeks (when frozen once) *Exceptions :* - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 3 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 6 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (when frozen once)	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 Between (-25)-(-15) °C (when frozen once) Exception for bilirubin total & direct - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 3 hours Between 2-8 °C 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 6 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (when frozen once)

Device name

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	**JJY**- 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

ELITech Clinical Systems ELITROL I and ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.

Comparison to Predicate device

	ELITech Clinical Systems Device (ELITROL I / ELITROL II)	Predicate Device (Roche Precinorm U / Precipath U K041227)
Intended use	ELITech Clinical Systems ELITROL I and ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in accuracy control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Analyzers.	For *in vitro* diagnostic use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet
Format	Lyophilized human sera with constituents added as required to obtain desired components levels	Lyophilized human sera with constituents added as required to obtain desired components levels
Levels	Two levels	Two levels
Handling	Carefully open the vial, avoiding the loss of lyophilizate, 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.	Carefully open the bottle, avoiding the loss of lyophilizate, 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.

	ELITech Clinical Systems Device (ELITROL I / ELITROL II)	Predicate Device (Roche Precinorm U / Precipath U K041227)
Stability	Lyophilized: To store at 2-8°C and protected from light until the expiry date After reconstitution, the stabilities are : Between 15-25 °C : 12 hours Between 2-8 °C : 5 days Between (-25)-(-15) °C : 4 weeks (when frozen once) *Exceptions:* - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 4 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 8 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (when frozen once)	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 & direct as noted in package insert: - Stability of direct bilirubin (when stored protected from light): Between 15-25 °C: 4 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once) - Stability of total bilirubin (when stored protected from light): Between 15-25 °C: 8 hours Between 2-8 °C: 24 hours Between (-25)-(-15) °C: 2 weeks (when frozen once)

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 they met all acceptance criteria, demonstrating that the device is substantially equivalent to its respective predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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AUG 3 0 2011

Re: k112029
Trade Name: ELITech Clinical Systems ELICAL 2
ELITech Clinical Systems ELITROL I /II
Regulation Number: 21 CFR §862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Codes: JIX, JJY
Dated: July 14, 2011
Received: July 15, 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): K112029

Device Name: _____ ELITech Clinical Systems ELICAL 2

Indications for Use:

ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

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)

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

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

510(k) K112029

Indications for Use Form

510(k) Number (if known): K112029

Device Name: _____ ELITech Clinical Systems ELITROL I & ELITROL II

Indications for Use:

ELITech Clinical Systems ELITROL I & ELITROL II are multi-parametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra analyzers.

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)

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

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

510(k) K112029