



Food and Drug Administration
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Silver Spring, MD 20993-0002

ELITECH GROUP
C/O DEBRA HUTSON
VICE PRESIDENT REGULATORY AFFAIRS/ QUALITY AFFAIRS
21720 23RD DRIVE SE, SUITE 150
BOTHELL WA 98021

July 8, 2015

Re: K151552

Trade/Device Name: ELITech Clinical Systems ELICAL 2
ELITech Clinical Systems ELITROL I
ELITech Clinical Systems ELITROL II

Regulation Number: 21 CFR 862.1150

Regulation Name: Calibrator

Regulatory Class: II

Product Code: JIX, JJY

Dated: June 8, 2015

Received: June 9, 2015

Dear Debra 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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 Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
k151552

Device Name
ELITech Clinical Systems ELICAL 2

Indications for Use (Describe)

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 Pro Series Analyzers.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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Indications for Use

510(k) Number (if known)
k151552

Device Name
ELITech Clinical Systems ELITROL I
ELITech Clinical Systems ELITROL II

Indications for Use (Describe)

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 Pro Series Analyzers.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

ELITech Clinical Systems ELICAL 2
ELITech Clinical Systems ELITROL I & ELITROL II

1. Date: July 6, 2015
2. Submitter: ELITech Clinical Systems SAS
Zone Industrielle
61500 SEES
FRANCE
3. Contact Person: Debra K. Hutson
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Bothell, WA 98021
Phone: 425-482-5174
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Email: d.hutson@elitechgroup.com
4.
 - 4.a Device Description: ELITech Clinical Systems ELICAL 2
Classification: Class II
JIX
Clinical Chemistry
21 CFR 862.1150
 - 4.b Device Description: ELITech Clinical Systems ELITROL I and ELITROL II
Classification: Class I
JJY
Clinical Chemistry
21CFR862.1660
5.
 - 5.a Predicate Device: K033501
Roche Diagnostics
Calibrator for Diagnostics Systems (C f.a.s)
 - 5.b Predicate Device: K041127
Roche Diagnostics
Precinorm U & Precipath U

6.
6.a

Intended Use

ELITech Clinical Systems ELICAL 2

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 Pro Series Analyzers.

Special conditions for use statement(s):

Rx ONLY

This device is intended for professional use and *in vitro* diagnostic only. CAUTION: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Special instrument requirements:

For use with ELITech Clinical Systems Selectra Pro Series Analyzers. Performance data was obtained on the Selectra ProM and ProS Analyzers.

6.b

Intended Use

ELITech Clinical Systems ELITROL I and ELITROL II

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 Pro Series Analyzers.

Special conditions for use statement(s):

Rx ONLY

This device is intended for professional use and *in vitro* diagnostic only. CAUTION: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner.

Special instrument requirements:

For use with ELITech Clinical Systems Selectra Pro Series Analyzers. Performance data was obtained on the Selectra ProM and ProS Analyzers.

7.

Device Descriptions

7.a

ELITech Clinical Systems ELICAL 2

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

7.b ELITech Clinical Systems ELITROL I and ELITROL II

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.

Analyte submission history:

ELITech Clinical Systems ELICAL 2, ELITech Clinical Systems ELITROL I and ELITech Clinical Systems ELITROL II were initially cleared under k093883. Additional analytes were added to the labeling in k100263, k100525, k102993, k103376, k102647, k110780, k110830, k112029, k122083 and k122858. This submission adds values for constituents to enable the devices to be used for the calibration and control of tests for IRON FERENE (exempt) and MAGNESIUM XYLIDYL (previously cleared under k040508). The new constituents' values have been added to the labeling for ELICAL 2 and ELITROL I & II.

8. **Substantial Equivalence Information**

8.a **Calibrator**

1. Predicate Device Name
Calibrator for Diagnostics Systems (C f.a.s)
2. K033501
3. Comparison with predicate

Similarities

Parameter	<u>New Device</u> ELITech Clinical Systems ELICAL 2	<u>Predicate Device</u> Calibrator for Diagnostics Systems (C f.a.s), K033501
Intended use	ELITech Clinical Systems ELICAL 2 is a multi-parametric calibrator for <i>in vitro</i> diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Pro Series Analyzers.	Calibrator for automated systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers 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
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.

Parameter	<u>New Device</u> ELITech Clinical Systems ELICAL 2	<u>Predicate Device</u> Calibrator for Diagnostics Systems (C f.a.s), K033501
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.

Parameter	<u>New Device</u> ELITech Clinical Systems ELICAL 2	<u>Predicate Device</u> Calibrator for Diagnostics Systems (C f.a.s), K033501
Stability	<p>Lyophilized: To store at 2-8°C and protected from light until the expiry date</p> <p><i>After reconstitution, the stabilities are :</i> Between 15-25 °C : 8 hours Between 2-8 °C : 2 days Between (-25)-(-15) °C : 4 weeks (when frozen once)</p> <p><u>Exceptions :</u> - 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)</p> <p>- 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)</p>	<p>Lyophilized: Stable at 2-8°C up to expiration date.</p> <p>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)</p> <p><u>Exception for bilirubin total & direct</u></p> <p>- 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)</p> <p>- 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)</p>

8.b

Controls

1. Predicate Device Name
Precinorm U & Precipath U
2. K041127
3. Comparison with predicate

Similarities

Parameter	<u>New Device</u> ELITech Clinical Systems ELITROL I & II	<u>Predicate Device</u> Precinorm U & Precipath U, K041127
Intended use	ELITech Clinical Systems ELITROL I & ELITROL II are multi-parametric control sera for in vitro diagnostic use in quality control of quantitative	For <i>in vitro</i> diagnostic use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheet.

Parameter	<u>New Device</u> ELITech Clinical Systems ELITROL I & II	<u>Predicate Device</u> Precinorm U & Precipath U, K041127
	ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Pro Series Analyzers.	
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.
Stability	<p>Lyophilized: To store at 2-8°C and protected from light until the expiry date</p> <p>After reconstitution, the stabilities are :</p> <p>Between 15-25 °C : 12 hours Between 2-8 °C : 5 days Between (-25)-(-15) °C : 4 weeks (when frozen once)</p> <p><u>Exceptions:</u></p> <p>- Stability of direct bilirubin (when stored protected from light):</p> <p>Between 15-25 °C: 4 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once)</p> <p>- Stability of total bilirubin (when stored protected from light):</p> <p>Between 15-25 °C: 8 hours Between 2-8 °C: 1 day Between (-25)-(-15) °C: 2 weeks (when frozen once)</p>	<p>Lyophilized: Stable at 2-8°C up to expiration date.</p> <p>After reconstitution, the stabilities* are :</p> <p>- 12 hours at 15-25 °C. - 5 days at 2-8 °C. - 4 weeks at (-25)-(-15) °C (when frozen once)</p> <p>*<u>Exception for bilirubin total & direct as noted in package insert:</u></p> <p>- Stability of direct bilirubin (when stored protected from light):</p> <p>Between 15-25 °C: 4 hours Between 2-8 °C: 8 hours Between (-25)-(-15) °C: 2 weeks (when frozen once)</p> <p>- Stability of total bilirubin (when stored protected from light):</p> <p>Between 15-25 °C: 8 hours Between 2-8 °C: 24 hours Between (-25)-(-15) °C: 2 weeks (when frozen once)</p>

9. **Stability**

ELITech Clinical Systems ELICAL 2 is purchased from a commercial vendor (previously cleared under k033501). The following is claimed for stability: ELICAL 2 is stable until the expiration date printed on the label when stored at 2-8°C prior to reconstitution. After reconstitution stability is 8 hours when stored at 15-25°C, 2 days at 2-8°C or 4 weeks between (-25)-(-15)°C (when frozen once). The labeling states that the ELICAL 2 should be stored tightly capped and protected from light when not in use

ELITech Clinical Systems ELITROL I & II is purchased from a commercial vendor (previously cleared under k041227). The following is claimed for stability: Before reconstitution, the shelf-life of the ELITech Clinical Systems ELITROL I and ELITROL II stored at 2-8°C is until the expiry date on the label. After reconstitution the stability is 12 hours when stored at 15-25°C, 5 days when stored at 2-8°C or 4 weeks between (-25)-(-15)°C (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).

10. **Value Assignment**

For each analyte requiring value assignment, the new lot of ELITech Clinical Systems ELICAL 2 is tested against the appropriate standard reference material on two separate ELITech Clinical Systems Selectra analyzers using the relevant ELITech Clinical Systems assay reagents. The mean analyte value is calculated and a target value is assigned on a minimum of 48 measurements taken. Verification of the value assignment is performed by calibrating with the new lot's assigned values and measuring quality control material at two levels and verifying that the values obtained are within the labeled range of the quality control.

For each analyte that requires value assignment, the new lot of ELITech Clinical Systems ELITROL I & II is tested using two separate ELITech Clinical Systems Selectra analyzers. Each sample is tested in triplicate over several days. The target value of Level I and II are the median of the observed values range. After validation of the target value, a confidence range (high and low values) is then calculated.

11. **Standard/Guidance Document Reference**

No applicable mandatory performance standards or special controls exist for this device.

12. **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 devices are substantially equivalent to their respective predicate devices.