SECTION 7 - 510(k) Summary

SEP 14 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: K111996

Submitter	ELITechGroup 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	July 8th, 2011

Device names

REAGENT

Trade/proprietary Name:	**ELITech Clinical Systems ISE CONTROL I and ISE CONTROL II**
Common or Usual Name:	**"ISE CONTROL I & ISE CONTROL II"**
Device Class	Class I
Classification name	CFR 862.1660 – Quality control material (assayed and unassayed)
Product code	**JJY** – multi-analyte controls, all kinds (assayed)

Predicate device	Biorad-Lyphochek Assayed Chemistry Control Level 1 and 2.(K040273)

Device description	ELITech Clinical Systems ISE CONTROL I and ISE CONTROL I are two level quality control products consisting of lyophilized human serum with added constituents of purified biochemicals chemicals, therapeutic drugs , preservatives and stabilizers . ISE CONTROL I and ISE CONTROL 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.
Intended Use	ELITech Clinical Systems ISE CONTROL I and ISE CONTROL II are control sera for in vitro diagnostic use in quality control of ELITech Clinical Systems ISE Na, K, Cl, Total CO2 on ELITech Clinical Systems Selectra analyzers equipped with ISE module.

Comparison to Predicate device

	ELITech Clinical Systems Device (ISE CONTROL I & ISE CONTROL II)	Predicate device (Biorad-Lyphochek Assayed Chemistry Control Level 1 and Level 2 (K040273))
Intended use	ELITech Clinical Systems ISE CONTROL I and ISE CONTROL II are control sera for in vitro diagnostic use in quality control of ELITech Clinical Systems ISE Na, K, Cl, Total CO_2 on ELITech Clinical Systems Selectra analyzers equipped with ISE module.	Lyphochek Assayed Chemistry Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Format	Lyophilized human serum	Lyophilized human serum
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.	Using a volumetric pipet, reconstitute each vial with 5.0 mL of distilled or deionized water. Replace the stopper and allow the control to stand for 20 minutes, swirling occasionally.
Stability	Prior to reconstitution, when stored at 2-8 °C and protected from light, the controls are stable until the expiry date stated on the label. After reconstitution : Between 2-8 °C: 7 days Between -20 and -10 °C: 28 days (when frozen once) Note : Store control sera tightly capped and protected from light after reconstitution.	When stored unopened the product is stable at until the expiration date at 2-8°C. Once the control is reconstituted all the analytes are stable 7 days when stored tightly capped at 2-8°C and 30 days at -10 to -20°C. Once thawed, do not refreeze.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

SEP 1 4 2011

ELITech Group
c/o Debra Hutson
21720 23rd Dr SE, Suite 150
Bothell, WA 98021

Re: k111996
Trade Name: ELITech Clinical Systems ISE Control I and Control II
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality Control Material (Assayed and Unassayed)
Regulatory Class: Class I, Reserved
Product Codes: JJY
Dated: September 6, 2011
Received: September 7, 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 Part 801), 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 postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. 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) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias, 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): K111996

Device Name: _____ ELITech Clinical Systems ISE CONTROL I
ELITech Clinical Systems ISE CONTROL II

Indications for Use:

ELITech Clinical Systems ISE CONTROL I and ISE CONTROL II are control sera for *in vitro* diagnostic use in quality control of ELITech Clinical Systems ISE Na, K, Cl, Total CO_2 on ELITech Clinical Systems Selectra analyzers equipped with ISE Module.

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) K111996