DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 7, 2016

ELITECHGROUP
TERRY TRIMINGHAM
REGULATORY ASSOCIATE
21720 23RD DRIVE SE, SUITE 150
BOTHELL, WA 98021

Re: K153644
Trade/Device Name: ELITech Clinical Systems GLUCOSE HK SL
ELITech Clinical Systems ELICAL 2
ELITech Clinical Systems ELITROL I
ELITech Clinical Systems ELITROL II
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: II
Product Code: CFR, JIX, JJY
Dated: July 25, 2016
Received: July 26, 2016

Dear Terry Trimingham:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153644

Device Name
ELITech Clinical Systems GLUCOSE HK SL
ELITech Clinical Systems ELICAL 2
ELITech Clinical Systems ELITROL I, ELITech Clinical Systems ELITROL II

Indications for Use *(Describe)*
ELITech Clinical Systems GLUCOSE HK SL is intended for the quantitative in vitro diagnostic determination of glucose in human serum, plasma and urine using ELITech Clinical Systems Selectra Pro Series Analyzers.

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

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 Analyzers.

ELITech Clinical Systems ELITROL I & ELITROL II are multiparametric control sera for in vitro diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems 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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K153644

510(k) Summary
Submitted in accordance with CFR 807.92

ELITech Clinical Systems GLUCOSE HK SL

1.	Date:	August 16, 2016
2.	Submitter:	ELITech Clinical Systems SAS Zone Industrielle 61500 SEES FRANCE
3.	Contact Person:	Terry Trimingham 21720 23rd Dr SE, Suite 150 Bothell, WA 98021 Phone: 425-482-5190 Fax: 425-482-5550 Email: t.trimingham@elitechgroup.com
4.	Device Description: Classification	ELITech Clinical Systems GLUCOSE HK SL Class II CFR Glucose HK Clinical Chemistry 21 CFR 862.1345
	Device Description: Classification	ELITech Clinical Systems ELICAL 2 Class ll JIX Clinical Chemistry 21 CFR 862.1150
	Device Description: Classification	ELITech Clinical Systems ELITROL l and ELITROL ll Class I JJY Clinical Chemistry 21 CFR 826.1660
5.	Predicate Device:	K951595 Roche Diagnostics Cobas C111 Glucose HK

6. Intended Use

Reagent:	ELITech Clinical Systems GLUCOSE HK SL is intended for the quantitative *in vitro* diagnostic determination of glucose in human serum, plasma and urine on ELITech Clinical Systems Selectra Pro Series Analyzers. Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic diseases.
Calibrators:	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 Analyzers.
Controls:	ELITech Clinical Systems ELITROL I and ELITROL II are multiparametric control sera for *in vitro* diagnostic use in quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Analyzers.

Special conditions for use statement(s):

This device is intended for prescription use and in vitro diagnostic only.

CAUTION: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner. It is not intended for use in Point of Care settings.

Reagent Special instrument requirements:
For use with ELITech Clinical Systems Selectra Pro Series Analyzers. Performance data was obtained on the Selectra ProM Analyzer.

7. **Device Descriptions**

ELITech Clinical Systems GLUCOSE HK SL is available as a kit only. It consists of a Bi-reagent R1 & R2 whose composition is: **R1:** Pipes buffer, pH 7.60 80 mmol/L, NAD 4.1 mmol/L, ATP 2.2 mmol/L, Sodium azide < 0.1 %
R2: Hexokinase ≥ 8 500 U/L, G-6-PDH ≥ 8 500 U/L, Magnesium salt 20 mmol/L, Sodium azide < 0.1 % mmol/L.

ELITech Clinical Systems ELICAL2 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 the antibodies to HCV and HIV according to FDA-approved methods.

ELITech Clinical Systems ELITROL I and ELITROL II are two level quality control products consisting of a 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.

8. **Substantial Equivalence Information**
Assay (reagent)

1. Predicate Device Name
   Roche Diagnostics Cobas C111 Glucose HK
2. K951595
3. Comparison with predicate

Similarities

Parameter	New Device ELITech Clinical Systems GLUCOSE HK SL	Predicate Device ROCHE DIAGNOSTICS GLUCOSE HK, K951595
Intended Use	ELITech Clinical Systems GLUCOSE HK SL is intended for the quantitative in vitro diagnostic determination of glucose in human serum, plasma and urine on ELITech Clinical Systems Selectra Pro Series Analyzers.	In vitro test for the quantitative determination of glucose in human serum, plasma and urine on the Cobas c 111 system.
Indication for Use	Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus and idiopathic hypoglycemia, and of pancreatic diseases.	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 tumors.
Sample Type	Serum, Plasma, Urine	Same
Assay Technology	Enzymatic (hexokinase). UV. End point.	Enzymatic reference method with hexokinase
Composition	Reagent : **R1:** Pipes buffer, pH 7.60 80 mmol/L, NAD 4.1 mmol/L, ATP 2.2 mmol/L, Sodium azide < 0.1 % **R2:** Hexokinase ≥ 8 500 U/L, G-6-PDH ≥ 8 500 U/L, Magnesium salt 20 mmol/L, Sodium azide < 0.1 %.	**R1:** TRIS buffer: 100 mmol/L, pH 7.8; Mg^{2+}: 4 mmol/L; ATP: ≥ 1.7 mmol/L; NADP: ≥ 1.0 mmol/L; preservative. **SR:** HEPES buffer: 30 mmol/L, pH 7.0; Mg^{2+}: 4 mmol/L; HK (yeast): ≥ 130 µkat/L; G‑6‑PDH (E. coli): ≥ 250 µkat/L; preservative.
Appearance of reagents	Liquid form, ready to use	Same

Differences

Parameter	New Device ELITech Clinical Systems GLUCOSE HK SL	Predicate Device ROCHE DIAGNOSTICS GLUCOSE HK, K951595
Assay Format	8 x 25 mL	4 x 100 mL
Storage & Expiry	Store at 2-8°C and protect from light. The reagent is stable until the expiry date stated on the label.	Shelf life at 2-8°C. See expiration date on reagent.
Assay Range	Serum, Plasma : 20 – 720 mg/dL Urine: 10 – 720 mg/dL	Serum, Plasma, Urine : 1.98 – 720 mg/dL
Instrument	Selectra Series Analyzers	Cobas C111
Reference	**Serum/ Plasma :**	**Serum / Plasma :** 74 - 109 mg/dL (4.11 – 6.05 mmol/L)

Parameter	New Device ELITech Clinical Systems GLUCOSE HK SL	Predicate Device ROCHE DIAGNOSTICS GLUCOSE HK, K951595
Values	74 - 106 mg/dL 4.1 – 5.9 mmol/L **Urine :** <0.5 g/day 1-15 mg/dL <2.78 mmol/day 0.1 - 0.8 mmol/L	 **Urine :** 1st Morning Urine: 6 - 20 mg/dL (0.3 – 1.1 mmol/L) 24 Hour Urine: 6 - 17 mg/dL (0.3 – 0.96 mmol/L) (Average of 1350 mL Urine/24 h)
Controls	Recommended quality control material (not included): ELITech Clinical Systems ELITROL I (Normal control) ELITech Clinical Systems ELITROL II (Pathologic control)	Recommended quality control material (not included): Precinorm U or Precinorm U plus and Precipath U or Precipath U plus
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): Calibrator f.a.s
Limit of Detection	Serum: 0.3 mg/dL (0.02 mmol/L) Urine: 0.2 mg/dL (0.01 mmol/L)	Serum, Plasma & Urine: 1.98 mg/dL (0.11 mmol/L)
Interferences- Serum	**Unconjugated bilirubin:** No significant interference up to 30.0 mg/dL (513 µmol/L). **Conjugated bilirubin:** No significant interference up to 29.5 mg/dL (504 µmol/L). **Hemoglobin**: No significant interference up to 500 mg/dL. **Triglycerides:** No significant interference up to 600 mg/dL (5.95 mmol/L). At a level of ~1300mg/dL of Triglycerides, a negative bias of 32% is observed at 50 mg/dL of glucose, and a negative bias of 19% is observed at 120mg/dL of glucose **Ascorbic acid:** No significant interference up to 20.0 mg/dL. (1136 µmol/L) **Uric acid:** No significant interference up to 20.0 mg/dL.(1190 µmol/L) **Methyl dopa:** No significant interference up to 2.0 mg/dL. **L-dopa:** No significant interference up to 30.0 mg/dL. **Tolazamide**: No significant interference up to 50.0 mg/dL. **Acetaminophen**: No significant interference up to 30 mg/dL. (1.98 mmol/L)	**Icterus:** No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL). **Hemolysis:** No significant interference up to an H index of 1000 (approximate hemoglobin concentration: 621 µmol/L or 1000 mg/dL). **Lipemia (Intralipid)**: No significant interference up to an L index of 2000. There is poor correlation between the L index (corresponds to turbidity) and Triglycerides concentration. **Drugs:** No interference was found at therapeutic concentrations using common drug panels.

Parameter	New Device ELITech Clinical Systems GLUCOSE HK SL	Predicate Device ROCHE DIAGNOSTICS GLUCOSE HK, K951595
Interferences - Urine	**Conjugated bilirubin:** No significant interference up to 29.5 mg/dL (504 µmol/L). **Hemoglobin**: No significant interference up to 500 mg/dL **Uric Acid:** No significant interference up to 100 mg/dL.(5.95 mmol/L) **Urea:** No significant interference up to 6000 mg/dL.(999 mmol/L) **pH:** No significant interference between 2.5 to 12.0 **Specific gravity:** No significant interference between 1.000 to 1.030	**No data**
Calibration frequency	Calibration frequency: 28 days Recalibrate when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.	Each lot and as required following quality control procedures.

Control Sera

1. Predicate Device Name:
   Roche Diagnostics Precinorm U and Precipath U
2. k041227

3. Comparison with predicate

Similarities and Differences

Item	ELITech Clinical Systems Device ELITROL I and ELITROL II	Predicate Roche Diagnostics Precinorm U and Precipath U (k041227)
Intended Use/Indications for 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 Analyzers.	Precinorm U is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets. Precipath U is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.
Format	Lyophilized human sera with constituents added as required to obtain defined component levels	Same
Levels	Two Levels (Level I and Level II)	Same
Stability	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)	Same

Calibrator

1. Predicate Device Name:
   Roche Diagnostics Calibrator for Automated Systems (C.f.a.s)
2. k033501
3. Comparison with predicate

Similarities and Differences

Item	ELITech Clinical Systems Device ELICAL 2	Predicate Roche Calibrator for Automated Systems (C.f.a.s.) k033501
Intended Use/Indications for Use	ELITech Clinical Systems ELICAL 2 is a multiparametric calibrator for *in vitro* diagnostic use in the calibration of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems 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 requires to obtain desired component levels	Same
Level	Single Level	Same
Stability	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)	Same

9. **Standard/Guidance Document Reference**
   - CLSI EP5-A2 (Evaluation of precision performance of Quantitative MeasurementMethods; Approved Guideline – Second Edition).
     CLSI protocol EP6-A (Evaluation of the Linearity of Quantitative Measurement Procedure: A Statistical Approach; Approved Guideline).
   - CLSI protocol EP17-A (Protocols for Determination of Limits of Detection and Limits of Quantification; Approved Guideline).
   - CLSI protocol EP7-A2 (Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition) used for recommended sample concentrations.
   - CLSI protocol EP9-A2 (Method Comparison and Bias Estimation Using Patient Samples ; Approved Guideline – Second edition).
   - NF EN 13640:2002 “Stability testing of in vitro diagnostic reagents
10. **Test Principle:**

    The reaction of glucose with ATP produces Glucose –6-phosphate which in presence of NAD+ will produce D-Gluconate-6-phosphate + NADH + H^+

    The increase of absorbance is directly proportional to the glucose concentration.

11. **Performance Characteristics – Analytical Performance**

    a. Precision/Reproducibility

Precision

The precision of the device was determined in accordance to CLSI EP05-A2 protocol (Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition).

Within-run and total precision results were obtained by performing two runs per day, two measures per run, for 4 levels of samples on 2 instruments during twenty operating days according to CLSI EP05-A2 protocol. The results are presented in the table below:

Serum
Level 1,2 and 4 are human sera, level 3 is a control sera

Level	n	Mean (mg/dL)	Precision %	
			Within-run CV%	Total CV%
Level 1	80	45.5	1.1	2.0
Level 2	80	119.5	0.9	1.7
Level 3	80	251.5	0.9	2.0
Level 4	80	522.5	0.4	1.8

Urine
Level 1 ,2 and 3 are urine pool

Level	n	Mean (mg/dL)	Precision %	
			Within-run CV%	Total CV%
Level 1	80	18.0	0.9	2.0
Level 2	80	204.4	0.7	1.7
Level 3	80	497.4	0.6	1.7

b. Linearity/assay reportable range

The linearity study of ELITech Clinical Systems GLUCOSE HK SL was performed according to CLSI protocol EP06-A (Evaluation of the Linearity of the Measurement of Quantitative Procedures: a Statistical Approach; Approved Guideline).

Serum:
The linearity of ELITech Clinical Systems GLUCOSE HK SL was studied by mixing a sample with high value (726.6 mg/dL) and a sample with low value (20.0 mg/dL) to obtain 11 levels with equidistant concentrations and then measuring the glucose concentration of each of the 11 levels using ECS GLUCOSE HK SL reagent.

Regression analysis of the results yielded the following:
$y = 1.025x – 2.0$ mg/dL.
$r = 1.000$
$r^2 = 1.000$
Standard error of the estimate $Sy.x = 2.0$ mg/dL

From this study, a measuring range from 20 – 720 mg/dL has been determined.

Urine:
The linearity of ELITech Clinical Systems GLUCOSE HK SL was studied by mixing a sample with high value (724.9 mg/dL) and a sample with low value (10.1 mg/dL) to obtain 11 levels with equidistant concentrations and then measuring the glucose concentration of each of the 11 levels using ECS GLUCOSE HK SL reagent.

Regression analysis of the results yielded the following:
y = 1.0155x – 1.6 mg/dL.
r = 0.999
r^2 = 0.998
Standard error of the estimate Sy.x = 3.5 mg/dL

From this study, a measuring range from 10 – 720 mg/dL has been determined.

Auto-dilution 1 to 5 allows the use of the ELITech Clinical Systems GLUCOSE HK SL with analyte activities up to 3600 mg/dL.

c. Traceability
For calibration, a multi-parametric calibrator, most recently cleared under k151552, named ELITech Clinical Systems ELICAL 2 (manufactured by ELITech Clinical Systems SAS under product code CALI-0580) must be used. Traceability of the assigned value for all constituents in this calibrator, including the glucose value assigned to calibrate ELITech Clinical Systems GLUCOSE HK SL, is included in its labeling. ELITech Glucose Hexokinase method is traceable to Isotope-dilution/Mass spectrometry, validated through the testing of SRM 965b of National Institute of Standards and Technology (NIST).

d. Stability

On board stability for the ELITech Clinical Systems GLUCOSE HK SL was established by real time studies on the ELITech Clinical Systems Selectra ProM Analyzer. The on-board stability of the reagent is 28 days. The shelf-life of GLUCOSE HK SL reagent has been followed in real time for 36 months on 3 different batches; a real-time stability of 27 months is claimed.

Serum control material 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 is 24 months at 2-8°C. After reconstitution the stability is 12 hours when stored at 15-25°C, 5 days when stored at 2-8°C or 4 weeks (when frozen once) at -25° and -15° C.

Calibrator material is purchased from a commercial vendor (previously cleared under k033501). The following is claimed for stability: Before reconstitution, the shelf-life of ELITech Clinical Systems Elical 2 is stable 24 months at 2-8°C. After reconstitution the stability is 8 hours when stored at 15-25°C, 2 days at 2-8°C or 4 weeks (when frozen once) at -25°and -15°C. The labeling states that the Elical 2 should be stored tightly capped and protected from light when not in use.

Value Assignment
Elitrol I and II are value assigned using multiple ELITech Clinical Systems Selectra ProM Series 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.

Elical 2 is tested against predetermined values on one ELITech Clinical Systems Selectra ProM Series Analyzers using the GLUCOSE HK SL reagent and 2 levels of quality control material. The mean analyte value is calculated and a target value is assigned.

e. Detection limit

Determined according to CLSI protocol EP17-A (Protocols for Determination of Limits of Detection and Limits of Quantification; Approved Guideline).

Serum

Limit of Detection:
The limit of Detection was obtained from 15 measurements of 4 samples prepared from 4 patient samples measured using ELITech Clinical Systems GLUCOSE HK SL and diluted with NaCl 0.9% to obtain a concentration of approximately 5 mg/dL.
The data are not Gaussian, so LoD= LoB + $D_{S,\beta}$ (where $D_{S,\beta}$ is determined by calculating the median minus the 5^{th} percentile of the low activity sample distribution).

Limit of Detection = 0.3 mg/dL.

Limit of Quantification:
The limit of Quantification was obtained from 15 measurements of 4 samples prepared from 4 patient samples measured using ELITech Clinical Systems GLUCOSE HK SL and diluted with NaCl 0.9% to obtain a concentration of 5.0 mg/dL.
Acceptance criteria: The acceptable Total Error for the determination Limit of Quantification is ≤ 0.32 mg/dL. If the confidence Interval is within the acceptable total error limits, then the Limit of Quantification is acceptable. The value must be equal or higher than the Limit of Detection.

Limit of Quantification = 5.00 mg/dL.

Urine

Limit of Detection:
The limit of Detection was obtained from 15 measurements of 4 samples prepared from 4 patient samples measured using ELITech Clinical Systems GLUCOSE HK SL and diluted with NaCl 0.9% to obtain a concentration of 5.0 mg/dL.
The data are not Gaussian, so LoD= LoB + $D_{S,\beta}$ (where $D_{S,\beta}$ is determined by calculating the median minus the 5^{th} percentile of the low activity sample distribution).

Limit of Detection = 0.2 mg/dL.

Limit of Quantification
The limit of Quantification was obtained from 15 measurements of 4 samples prepared from 4 patient samples measured using ELITech Clinical Systems GLUCOSE HK SL and diluted with NaCl 0.9% to obtain a concentration of 1.50 mg/dL.
Acceptance criteria: The acceptable Total Error for the determination Limit of Quantification is ≤ 0.8 mg/dL. If the confidence Interval is within the acceptable total error limits, then the Limit of Quantification is acceptable. The value must be equal or higher than the Limit of Detection.

Limit of Quantification =5.00 mg/dL.

f. Interference/analytical specificity

Serum

Interferences due to unconjugated bilirubin, conjugated bilirubin, hemoglobin, triglycerides, ascorbic acid, uric acid, methyl dopa, L-dopa, Tolazamide and acetaminophen were investigated following the recommended sample levels in CLSI EP07-A2 protocol

(Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition).

For each potential interferent tested, 2 serum sample pools at two glucose levels close to those specified in Appendix B of EP7-A2 were prepared:
-1st pool: low activity at nominal 50.0 mg/dL
-2nd pool: high activity at nominal 120.0 mg/dL
Aliquots of each of the serum sample pools were spiked with increasing interferent concentration. Test ranges covered at least the interferent level specified in Appendix D of EP7-A2. Thus, there were two series of interferent spike for each potential interferent tested. A control sample was prepared from the sample pool diluted in the appropriate diluent.

Interferent	Test range	Number of different concentrations tested
Triglycerides	up to 3000 mg/dL	9
Unconjugated bilirubin	up to 30.0 mg/dL	7
Conjugated bilirubin	up to 29.5 mg/dL	7
Hemoglobin	up to 500 mg/dL	9
Uric acid	up to 20.0 mg/dL	7
L-dopa	up to 30 mg/dL	7
Ascorbic acid	up to 20 mg/dL	7
Methyl dopa	up to 2.0 mg/dL	6
Tolazamide	up to 50 mg/dL	6
Acetaminophen	up to 30 mg/dL	7

Two (2) levels of control (Serum control Level 1 (ELITROL I) and Serum control Level 2 (ELITROL II)) were tested to check the calibration.

For both sample pools for each interferent, each point was measured in triplicate per run.

Acceptance criteria: an accepted bias of ±10% in sample pools with low (50.0 mg/dL) or high (120.0 mg/dL) nominal activity.

The results of testing interferences are the following:

- Concentration up to 30.0 mg/dL unconjugated bilirubin, 29.5 mg/dL conjugated bilirubin, 500 mg/dL hemoglobin, 600 mg/dL triglycerides (At a level of ~1300mg/dL of Triglycerides, a negative bias of 32% is observed at 50 mg/dL of glucose, and a negative bias of 19% is observed at 120mg/dL of glucose), 20.0 mg/dL ascorbic acid, 20.0 mg/dL uric acid, 2.0 mg/dL methyl dopa, 30.0 L-dopa, 50.0 Tolazamide and 30 mg/dL acetaminophen do not show any significant interference for each substance.
- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.

The following statement will also be included in the labeling:

Many other substances and drugs may interfere. Some of them are listed in Young.
-Young, D. S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).
-Young, D. S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).
-Berth, M. & Delanghe, J. *Protein precipitation as a possible important pitfall in the clinical chemistry analysis of blood samples containing monoclonal immunoglobulins: 2 case reports and a review of literature*, Acta Clin Belg., (2004), **59**, 263.

Urine
Interferences due to Conjugated bilirubin, Hemoglobin, Uric Acid and Urea were investigated following the recommended sample levels in CLSI EP07-A2 protocol (Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition)**.** Also tested were pH and specific gravity.

For each potential interferent tested, 2 urine sample pools at two glucose levels close to those specified in Appendix B of EP7-A2 were prepared:
-1st pool: low activity at nominal 18.0 mg/dL
-2nd pool: high activity at nominal 200.0 mg/dL
Aliquots of each of the urine sample pools were spiked with increasing interferent concentration. Test ranges covered at least the interferent level specified in Appendix D of EP7-A2. Thus, there were two series of interferent spike for each potential interferent tested. A control sample was prepared from the sample pool diluted in the appropriate diluent.

Interferent	Test range	Number of different concentrations tested
Conjugated bilirubin	up to 29.5 mg/dL	7
Hemoglobin	up to 500 mg/dL	9
Uric acid	up to 100 mg/dL	6
Urea	up to 6000 mg/dL	6
pH	between 2.5 to 12.0	7
Specific Gravity	between 1.000 to 1.030	6

Two (2) levels of control (Serum control Level 1 (ELITROL I) and Serum control Level 2 (ELITROL II)) were tested to check the reagents.

For both sample pools for each interferent, each point was measured in triplicate per run.

Acceptance criteria: an accepted bias of ±10% in sample pools with low (18.0 mg/dL) or high (200.0 mg/dL) nominal activity.

The results of testing interferences are the following:

- Concentration up to 29.5 mg/dL conjugated bilirubin, 500 mg/dL hemoglobin, 100 mg/dL uric acid and 6000 mg/dL urea do not show any significant interference for each substance.

The following statement will also be included in the labeling:

Many other substances and drugs may interfere. Some of them are listed in Young.
-Young, D. S., Effects of preanalytical variables on clinical laboratory tests, 2nd Ed., AACC Press, (1997).
-Young, D. S., Effects of drugs on clinical laboratory tests, 4th Ed., AACC Press, (1995).

11. **Performance Characteristics – Comparison Studies**

a. Method comparison

Serum
A correlation study was performed between ELITech Clinical Systems GLUCOSE HK SL reagent on a Selectra ProM Analyzer and GLUC2 (Glucose HK) reagent on Cobas C111 analyzer according to CLSI EP09-A2 protocol (Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second edition).

This study was performed using 100 serum patient samples from 20.5 to 707.5 mg/dL over a span of 5 days.

Regression analysis of the results yielded the following:
$y = 1.008\ x + 0.4$ mg/dL.
$r = 1.000$
$r^2 = 1.000$
Standard error of the estimate Sy.x = 2.7 mg/dL.

Urine
A correlation study was performed between ELITech Clinical Systems GLUCOSE HK SL reagent on a Selectra ProM Analyzer and GLUC2 (Glucose HK) reagent on Cobas C111 analyzer according to CLSI EP09-A2 protocol (Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second edition)

This study was performed using 40 urine patient samples (with glacial acetic acid as preservative) from 10.1 to 703.9 mg/dL over a span of 2 days.

Regression analysis of the results yielded the following:
y = 0.996 x - 0.4 mg/dL
r = 1.000
r^2 = 1.000
Standard error of the estimate Sy.x = 3.5 mg/dL

b. Comparison study: Matrix comparison

40 plasma patients (in lithium heparin samples, ranging from 24.3 to 710.1 mg/dL), were tested on ELITech Clinical Systems Selectra ProM Analyzer according to CLSI protocol EP09-A2 (Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second edition).

Regression analysis of the results yielded the following:

y = 1.001x – 0.7 mg/dL
r = 1.000
r^2 = 1.000
Standard error of the estimate Sy.x = 1.9 mg/dL

40 plasma patients (in sodium fluoride/ oxalate, ranging from 21.2 to 701.4 mg/dL), were tested on ELITech Clinical Systems Selectra ProM Analyzer according to CLSI protocol EP09-A2 (Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second edition).

Regression analysis of the results yielded the following:

y = 1.016x – 0.9 mg/dL
r = 0.999
r^2 = 0.998
Standard error of the estimate Sy.x = 7.0 mg/dL

c. Expected values/Reference Range
As indicated in the instructions for use for ELITech Clinical Systems GLUCOSE HK SL, each laboratory should establish and maintain its own reference values. The values given are used as guidelines only.

Serum/ Plasma :
74 - 106 mg/dL
4.1 – 5.9 mmol/L

Urine :
<0.5 g/day 1-15 mg/dL
<2.78 mmol/day 0.1 - 0.8 mmol/L

These reference values are from:

Wu, A. H. B., Clinical guide to laboratory tests, 4ème Ed., (W.B. Saunders eds. Philadelphia USA), (2006), 444

d. Clinical Studies:

Not applicable

e. Clinical Cut-off:

Not applicable

12. **Conclusion**

Versus the predicate, the new device has the same indications for use on the same specimen types. The information on the principle and performance of the test device shown in the above table, gained in laboratory evaluation of the device and contained in this premarket notification, shows no deviation in safety or effectiveness, and supports a decision that the test device is substantially equivalent to the predicate device.