510(k) Summary JAN - 3 2014

ELITech Clinical Systems CREATININE PAP SL

1.	Date:	July 29, 2013
2.	Submitter:	ELITech Clinical Systems SAS Zone Industrielle 61500 SEES FRANCE
3.	Contact Person:	Debra K. Hutson Director, QARA, North America 21720 23rd Dr SE, Suite 150 Bothell, WA 98021 Phone: 425-482-5174 Fax: 425-482-5550 Email: d.hutson@elitechgroup.com
4.	Device Description: Classification	ELITech Clinical Systems CREATININE PAP SL Class II JFY Clinical Chemistry 21 CFR 862.1225
	Device Description: Classification	ELITech Clinical Systems ELICAL 2 Class II JIX Clinical Chemistry 21 CFR 862.1150
	Device Description: Classification	ELITech Clinical Systems ELITROL I and ELITROL II Class I, JJY Clinical Chemistry 21 CFR 826.1660
	Device Description: Classification	ELITech Clinical Systems URINE CONTROL BI-LEVEL Class I, JJY Clinical Chemistry 21 CFR 826.1660
5.	Predicate Device:	k024098 Roche Diagnostics Creatinine plus ver 2 k033501 Roche Diagnostics Calibrator for Automated Systems (C.f.a.s.) k041227 Roche Diagnostics Precinorm and Precipath

k020817
BIO-RAD
Liquichek Urine Chemistry Control Level 1 and Level 2

6. Intended Use

Reagents:

ELITech Clinical Systems CREATININE PAP SL is intended for the quantitative *in vitro* diagnostic determination of creatinine in human serum, plasma and urine on ELITech Clinical Systems Selectra Pro Series Analyzers. It is not intended for use in Point of Care settings.
Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

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 Selectra Pro Series Analyzers.

Controls:

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 Pro Series Analyzers.

ELITech Clinical Systems URINE CONTROL BI-LEVEL is a set of 2 levels of urine controls used for *in vitro* diagnostic in the quality control of quantitative ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Pro Series Analyzers.

Special conditions for use statement(s):
Prescription Use Only. It is not intended for use in Point of Care settings.

Special instrument requirements:
Performance was provided for the ELITech Clinical Systems Selectra ProM Analyzer.

7. **Device Descriptions**

ELITech Clinical Systems CREATININE PAP SL is available as kit only. It consists of a bi-reagent R1 and R2 whose composition is, for R1: MOPS buffer (pH 7.50), EHSPT, Creatinase, Sarcosine oxidase, Ascorbate oxidase. For R2: MOPS buffer (pH 7.50), 4-Aminoantipyrine, Creatininase, Peroxidase, sodium azide.

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.

ELITech Clinical Systems URINE CONTROL BI-LEVEL is a liquid solution prepared from human urine supplemented with constituents of human and animal origin, chemicals, preservatives and stabilizers. Human sera corresponding to the URINE CONTROL BI-LEVEL were tested for each urine donor and found to be negative for HbsAg and antibodies to HCV and HIV-1/HIV-2 according to FDA-approved methods.

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

1. Predicate Device Name
   Roche Diagnostics Creatinine plus ver.2
2. k024098
3. Comparison with predicate

Similarities

Parameter	ELITech Clinical Systems Device CREATININE PAP SL	Predicate device Roche Diagnostics Creatinine plus ver.2
Intended Use / Indication for Use	Intended for the quantitative *in vitro* diagnostic determination of creatinine in human serum, plasma and urine on ELITech Clinical Systems Selectra Pro Series Analyzers. It is not intended for use in Point of Care settings. Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.	For *in vitro* diagnostic use in the quantitative determination of creatinine in serum, plasma and urine on the cobas c111 system.
Specimen Type	Serum, Plasma, Urine	Same
Assay Technology	Enzymatic colorimetric test	Same

Differences

Parameter	ELITech Clinical Systems Device CREATININE PAP SL	Predicate device Roche Diagnostics Creatinine plus ver.2
Assay Range	Serum/plasma: 0.10 – 30 mg/dL Urine: 5 – 450 mg/dL.	Serum/plasma: 0.06 – 30.5 mg/dL Urine: 1.1 - 452 mg/dL.
Instrument	Selectra ProM analyzer	cobas c111
Calibrator	Recommended calibration material (not included): ELITech Clinical Systems ELICAL 2	Recommended calibration material (not included): Roche Calibrator f.a.s.
Interferences- Serum/Plasma	Serum/Plasma Unconjugated bilirubin: No significant interference up to 30.0 mg/dL. Conjugated bilirubin: No significant interference up to 14.8 mg/dL. Hemoglobin: No significant interference up to 500 mg/dL. Triglycerides: No significant interference up to 3000 mg/dL. Uric acid: No significant interference up to 20.0 mg/dL. Glucose: No significant interference up to 500 mg/dL. Ascorbic acid: No significant interference up to 20 mg/dL. Methyl-dopa: Induce falsely low results at therapeutic concentrations. L-dopa: Induce falsely low results at therapeutic concentrations. Calcium dobesilate: Induce falsely low results at therapeutic concentrations. Creatine: No significant interference up to 5 mg/dL.	Serum/Plasma Icterus: No significant influence up to I Index of 20 (approximate conjugated and unconjugated bilirubin concentration of 20 mg/dL (342 µmol/L)). Hemoglobin: No significant interference up to an H Index of 800 (approximate 800 mg/dL). Lipemia (Intralipid): No significant influence up to an L index of 1000. There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration. Ascorbic acid: < 300 mg/L does not interfere. Drugs: No interference was found at therapeutic concentrations using common drug panels. Exceptions: Levodopa and calcium dobesilate cause artificially low creatinine levels at the tested drug level while DL-proline at a concentration of >1mmol/L causes falsy high results. 2-Phenyl-1,3 indandion (Phenindion) at therapeutic concentrations interference with the assay. Cyanokit (Hidroxocobalamin) may cause interference with results.

Parameter	ELITech Clinical Systems Device CREATININE PAP SL	Predicate device Roche Diagnostics Creatinine plus ver.2
		Other: In very rare cases monoclonal gammopathy can lead to incorrect results. No significant interference up to a creatine level of 0.38 mmol/L (5 mg/dL).
Interferences - Urine	Urine Conjugated bilirubin: No significant interference up to 29.5 mg/dL. Hemoglobin: No significant interference up to 500 mg/dL. Ascorbic acid: No significant interference up to 20 mg/dL. Methyl-dopa: No significant interference up to 10 mg/dL. Calcium dobesilate: No significant interference up to 50.0 mg/dL Glucose: No significant interference up to 5000 mg/dL.	Urine Drugs: No interference was found at therapeutic concentration using common drugs panels. Exception: Levodopa causes artificially low results. High homogentisic acid concentrations in urine samples lead to false results. Other: No significant interference up to a creatinine level of 3.05 mmol/L (40 mg/dL)
Reference Range	**Serum/plasma:** Adults : Females 0.55 – 1.02 mg/dL Males 0.72 – 1.18 mg/dL **Urine:** Females 11 – 20 mg/kg/24h Males 14 – 26 mg/kg/24h	**Serum/plasma:** Adults : Females 0.51 – 0.95 mg/dL Males 0.67 – 1.17 mg/dL Children: Neonates(premat.) 0.33-0.98 mg/dL Neonates(full term) 0.31-0.88 mg/dL 2-12 m 0.16-0.39 mg/dL 1-< 3 y 0.18-0.35 mg/dL 3-< 5 y 0.26-0.42 mg/dL 5-< 7 y 0.29-0.47 mg/dL 7-< 9 y 0.34-0.53 mg/dL 9-< 11 y 0.33-0.64 mg/dL 11-< 13 y 0.44-0.68 mg/dL 13-< 15 y 0.46-0.77 mg/dL **Urine** 1st morning urine Females 29 – 226 mg/dL Males 40 – 278 mg/dL 24h Urine Females 720 – 1510 mg/ 24 h Males 980 – 2200 mg/ 24 h

Parameter	ELITech Clinical Systems Device CREATININE PAP SL	Predicate device Roche Diagnostics Creatinine plus ver.2
Calibration frequency	Serum/Plasma: 14 days Urine: 14 days	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 Selectra Pro Series 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

Urine Control

1. Predicate Device Name:
   Biorad Liquichek Urine Chemistry Control Level 1 and Level 2
2. k020817
3. Comparison with predicate

Similarities and Differences

Item	ELITech Clinical Systems Device URINE CONTROL BI -LEVEL	Predicate Device Biorad Liquichek Urine Chemistry Control Level 1 and Level 2 (K020817)
Intended use	ELITech Clinical Systems URINE CONTROL BI - LEVEL is a set of 2 levels of urine controls for *in vitro* diagnostic used in the quality control of quantitative	Liquichek Urine Chemistry Control is intended for use as unassayed quality control urine.

Similarities and Differences

Item	ELITech Clinical Systems Device URINE CONTROL BI -LEVEL	Predicate Device Biorad Liquichek Urine Chemistry Control Level 1 and Level 2 (K020817)
	ELITech Clinical Systems methods on ELITech Clinical Systems Selectra Pro Series Analyzers	
Format	Liquid ready to use, a liquid solution prepared from human urine supplemented with constituents of human and animal origin, chemicals, preservatives and stabilizers.	Liquid form, prepared from prepared from human urine supplemented with constituents of human and animal origin, chemicals, preservatives and stabilizers.
Levels	Two levels	Same
Stability	- Before opening: Each control is stable until the expiry date stated on the label. - After opening: Each control is stable for 30 days when stored tightly-closed between 2-8 °C. - Creatinine values may gradually decrease over the product shelf life. Individual laboratory means may eventually fall outside of the corresponding ranges indicated in the value sheet included in the kit.	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 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.	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 requires to obtain desired component levels	Same
Level	Single Level	Same

Similarities and Differences

Item	ELITech Clinical Systems Device ELICAL 2	Predicate Roche Calibrator for Automated Systems (C.f.a.s.) k033501
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**

- Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition. CLSI (NCCLS) document EP05-A2, Vol 24, No. 25, August 2004.
- Protocols for Determination of Limits of Detection and Limits of Quantification; Approved Guideline. CLSI (NCCLS) document EP17-A, vol 24, No. 34, October 2004.
- Method Comparison and Bias estimation Using Patient Samples; Approved Guideline—Second Edition. CLSI (NCCLS) document EP09-A2-IR, Vol 30, No. 17, July 2010.
- Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use: Guidance for Industry and FDA Staff, November 2004.
- Interference Testing in Clinical Chemistry; Approved Guideline—Second Edition. CLSI (NCCLS) document EP07-A2, Vol 25, No. 27, November 2005.
- Evaluation of the Linearity of the Measurement of Quantitative Procedures: a Statistical Approach; Approved Guideline. CLSI (NCCLS) document EP06-A, Vol 23, No. 16, April 2003.

10. **Test Principle:**

Creatininase hydrolyzes creatinine in sample to creatine. Creatine is hydrolyzed by creatinase to sarcosine and urea. Sarcosine is then oxidized by sarcosine oxidase to produce hydrogen peroxide (H_2O_2). H_2O_2 reacts with 4-amino-antipyrine (4-AAP) and EHSPT (N-Ethyl-N-2(-Hydroxy-3-Sulfopropyl)-*m*- Toluidine) under the catalytic action of peroxidase to form a colored quinoneimine. The absorbance of the quinoneimine at 546 nm is proportional to the concentration of creatinine in the sample.

$$\text{Creatinine} + H_2O \xrightarrow{\textit{Creatininase}} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\textit{Creatinase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + O_2 \xrightarrow{\textit{Sarcosine oxidase}} \text{Glycine} + HCHO + H_2O_2$$

$$H_2O_2 + \text{EHSPT} + \text{4-AAP} \xrightarrow{\textit{Peroxidase}} \text{Quinoneimine}$$

4-AAP: Amino-4-antipyrine
EHSPT : N-Ethyl-N-2(-Hydroxy-3-Sulfopropyl)-*m*-Toluidine

11. **Performance Characteristics – Analytical Performance**

a. Precision/Reproducibility

The precision of the device was determined in accordance with Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition. CLSI (NCCLS) document EP05-A2, Vol 24, No. 25, August 2004.

Within-run and total precision results were obtained by performing two runs per day, two measures per run, for 3 levels of samples on 2 instruments during twenty operating days according to CLSI EP05-A2 protocol. The results are presented in the table below:

Precision

Serum/Plasma

Level	n	Mean (mg/dL)	Precision %	
			Within-run CV%	Total CV%
Level 1	80	0.76	1.2%	1.9%
Level 2	80	1.52	0.6%	1.7%
Level 3	80	5.52	0.5%	1.5%

Urine

Level	n	Mean (mg/dL)	Precision %	
			Within-run CV%	Total CV%
Level 1	80	83	0.8%	2.2%
Level 2	80	159	0.7%	2.3%
Level 3	80	308	1.9%	2.9%

b. Linearity/assay reportable range

The linearity study of CREATININE PAP SL reagent was performed according to CLSI protocol EP06-A.
Serum/Plasma: From this study, a measuring range from 0.10 to 30 mg/dL has been determined.
Manual dilution 1 to 5 allows an upper linearity of CREATININE PAP SL reagent to 150 mg/dL.

Urine: From this study, a measuring range from 5 to 450 mg/dL has been determined.

c. Traceability

For calibration, a multi-parametric calibrator named ELITech Clinical Systems ELICAL 2 (manufactured by ELITech Clinical Systems SAS under product code CALI-0580) must be used. Its value is traceable to the ID-MS (Isotope Dilution -Mass Spectrometry) reference method.

d. Stability

Real-time stabilities:
On board stability for the ELITech Clinical Systems CREATININE PAP SL was established by real time studies on the ELITech Clinical Systems Selectra Analyzer. The on-board stability of the reagent is 28 days. The shelf-life of CREATININE PAP SL reagent has been followed in the real time for 20 months on 3 different batches.

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 stated that the Elical 2 should be stored tightly capped and protected from light when not in use.

Urine control material is purchased from commercial vendor (preciously cleared under k020817). The following is claimed for stability: ELITech Clinical Systems URINE CONTROL BI-LEVEL is stable 10 months at 2-8°C. After opening, each control is stable for 30 days when stored tightly closed at 2-8°C.

d. Stability (continued)

Creatinine values may gradually decrease over the product shelf life. Individual laboratory means may eventually fall outside of the corresponding ranges indicated in the value sheet included in the kit.

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 CREATININE PAP SL reagent and 2 levels of quality control material. The mean analyte value is calculated and a target value is assigned.

URINE CONTROL BI-LEVEL value is assigned using multiple ELITech Clinical Systems Selectra Series Analyzers. 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.

e. Detection limit

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

Serum/Plasma

Limit of Detection (LoD) of CREATININE PAP SL obtained from 15 measurements of 4 samples with a low concentration of analyte (approximately 4 x LoB ≈ 0.04 mg/dL) is 0.02 mg/dL.

Limit of Quantification (LoQ) of CREATININE PAP SL obtained from 15 measurements of 4 samples at nominal concentration 0.08 md/dL is 0.08 mg/dL.

Urine

Limit of Detection (LoD) of CREATININE PAP SL obtained from 15 measurements of 4 samples with a low concentration of analyte is 0.5 mg/dL.

Limit of Quantification (LoQ) of CREATININE PAP SL obtained from 15 measurements of 4 samples is 2.0 mg/dL.

f. Interference/analytical specificity

Interferences due to unconjugated bilirubin, conjugated bilirubin, triglycerides, hemoglobin, ascorbic acid, uric acid, glucose, methyl-dopa, L-dopa, calcium dobesilate and creatine were investigated following the recommended sample levels in CLSI EP07-A2 protocol (Interference Testing in Clinical Chemistry; Approved Guideline – Second Edition).
The results of testing interferences are the following:

Serum/Plasma

- Concentration up to 30.0 mg/dL unconjugated bilirubin, 3000 mg/dL triglycerides, 500 mg/dL hemoglobin, 20.0 mg/dL Uric acid, 500 mg/dL Glucose, 20 mg/dL Ascorbic acid, 5 mg/dL Creatine, 14.8 mg/dL Conjugated bilirubin do not show any significant interference for each substance.
- Methyl-dopa, L-dopa and Calcium dobesilate induce falsely low results at therapeutic concentrations.
- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.

Urine

- Concentration up to 29.5 mg/dL Conjugated bilirubin, 500 mg/dL Hemoglobin, 20 mg/dL Ascorbic acid, 50.0 mg/dL Calcium dobesilate, 539 mg/dL Glucose, 10 mg/dL Methyl-dopa do not show any significant interference for each substance.

The following statement will also be included in the labeling:

Other compounds may interfere. Users should refer to the two following literature references:
-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.

12. **Performance Characteristics – Comparison Studies**

a. Method comparison

Serum/Plasma

A correlation study was performed between CREATININE PAP SL reagent on a Selectra Pro Series Analyzer and Roche Diagnostics CREP2 (Creatinine Plus ver 2) reagent on a 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 0.10 to 30.1 mg/dL over a span of 5 days.
Regression analysis of the results yielded the following:

$y = 0.979x + 0.05$ mg/dL.
$r = 1.000$
$r^2 = 1.000$
Standard error of the estimate $Sy.x = 0.09$ mg/dL.

Urine
54 urine patient samples ranging from 3 to 413 mg/dL, were tested on Selectra Pro Series 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 = 1.063x + 2 mg/dL
r = 1.000
r^2 = 0.999
Standard error of the estimate Sy.x = 4 mg/dL

b. Comparison study: Matrix comparison

43 plasma patients (in lithium heparin samples, ranging from 0.11 to 30.23 mg/dL), were tested on a Selectra Pro Series 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 = 0.981x + 0.03 mg/dL
r = 1.000
r^2 = 1.000
Standard error of the estimate Sy.x = 0.09 mg/dL.

c. Expected values/Reference Range

As indicated in the instructions for use for CREATININE PAP SL, each laboratory should establish and maintain its own reference values. The values given are used as guidelines only.

	Men	Woman	
Serum/ Plasma	0.72 – 1.18	0.55 – 1.02	mg/dL
	64 -104	49 -90	µmol/L
Urine	14 - 26	11 -20	mg/dL/kg/24h
	124 -230	97 -177	µmol/L/kg/24h

These reference values are from:
Newman, D.J., Price C.P., Tietz Fundamentals of Clinical Chemistry, 5th Ed., Burtis, C.A. & Ashwood, E.R. (W.B. Saunders eds. Philadelphia USA), (2001), 414.
Ceriotti, F., *Reference Intervals for Serum Creatinine Concentrations: Assessment of Available Data for Global Application.* Clin. Chem., (2008), **54**, 559.

d. Clinical Studies:

Not applicable

e. Clinical Cut-off:

Not applicable

13. **Conclusion**

The information on the principle and performance of our device that is contained in this premarket notification is complete and supports a decision that our device is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 3, 2014

ELITECH GROUP
DEBRA K. HUTSON
DIRECTOR, RA/QA, NORTH AMERICA
21720 23RD DR S.E., SUITE 150
BOTHELL WA 98021

Re: K132399
Trade/Device Name: ELITech Clinical Systems Creatinine PAP SL
ELITech Clinical Systems ELICAL 2
ELITech Clinical Systems ELITROL I and ELITech Clinical Systems ELITROL II
ELITech Clinical Systems URINE CONTROL BI-LEVEL
Regulation Number: 21 CFR 862.1225
Regulation Name: Creatinine test system
Regulatory Class: II
Product Code: JFY, JIX, JJY
Dated: December 4, 2013
Received: December 5, 2013

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. 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 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/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson -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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132399

Device Name
ELITech Clinical Systems CREATININE PAP SL
ELITech Clinical Systems ELICAL 2
ELITech Clinical Systems ELITROL I and ELITech Clinical Systems ELITROL II
ELITech Clinical Systems URINE CONTROL BI-LEVEL

Indications for Use *(Describe)*

ELITech Clinical Systems CREATININE PAP SL is intended for the quantitative in vitro diagnostic determination of creatinine in human serum, plasma and urine on ELITech Clinical Systems Selectra Pro Series Analyzers. It is not intended for use in Point of Care settings.

Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.

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.

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.

ELITech Clinical Systems URINE CONTROL BI- LEVEL is a set of 2 levels of urine controls used for in vitro diagnostic in the 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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