

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k112029

B. Purpose for Submission:

Claim of previously cleared analytes (ALP, ALT/GPT, Gamma-GT and LDH) for use on Elitech's test system under Elitech's label using previously cleared multi-analyte controls and calibrators

C. Measurand:

Calibrators and assayed controls for ALP, ALT/GPT, Gamma-GT and LDH

D. Type of Test:

Calibrators and Quality Control Material

E. Applicant:

ELITech Clinical Systems, SEPPIM S.A.S.

F. Proprietary and Established Names:

ELITech Clinical Systems ELITROL I

ELITech Clinical Systems ELITROL II

ELITech Clinical Systems ELICAL 2

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JIX Calibrator, Multi-analyte mixture	Class II	21 CFR 862.1150 Calibrator	Clinical Chemistry (75)
JJY Multi-analyte controls, all kinds (assayed)	Class I, reserved	21 CFR 862.1660 Quality control material (assayed and unassayed)	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

Refer to indication for use below

2. Indication(s) 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.

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.

3. Special conditions for use statement(s):

For prescription use

4. Special instrument requirements:

ELITech Clinical Systems Selectra analyzers

I. Device Description:

ELITech Clinical Systems purchases the below described products from a commercial vendor and re-label it for use with the Elitech test systems. These products were cleared under k033501 and k041227 sponsored by the supplier. Elitech did not change the content and the packaging except the labeling change.

ELITech Clinical Systems ELICAL 2 is a lyophilized calibrator based on human serum containing constituents to ensure optimal calibration.

ELITech Clinical Systems ELITROL I and ELITROL II are two level quality control products consisting of lyophilized human serum containing constituents at desired levels.

ELICAL 2, 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.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Roche Calibrator f.a.s.

Roche Precinorm U/Precipath U

2. Predicate 510(k) number(s):

Roche Calibrator f.a.s. (k033501)

Roche Precinorm U/Precipath U (k041227)

3. Comparison with predicate:

Characteristic	ELICAL 2 (New Device)	Roche Calibrator f.a.s. (Predicate Device, k033501)
Similarities		
Intended Use	Same	Is a multi-parametric calibrator used for calibration of quantitative assays
Format	Same	Lyophilized
Levels	Same	1
Handling	Same	Reconstitute with exactly 3.0 mL distilled or deionized water.
Matrix	Same	Human Serum
Stability	Same	Unopened: • Store at 2-8°C until expiration date Reconstituted: Between 15-25 °C : 12 hours Between 2-8 °C : 5 days Between (-25)-(-15) °C : 4 weeks (when frozen once)
Differences		
Labeling	Labeled under ELITech	Labeled under Roche
Claim	9 of the 16 analytes	16 analytes

Characteristic	Elitrol I/Elitrol II (New Device)	Roche Precinorm U/Precipath U (Predicate Device, k041227)
Similarities		
Intended Use	Same	Are multi-parametric control sera used in quality control of quantitative assays
Format	Same	Lyophilized
Matrix	Same	Human serum
Levels	Same	2
Handling	Same	Reconstitute with exactly 5.0 mL distilled or deionized water
Stability	Same	Unopened: • Store at 2-8°C until expiration date Reconstituted: Between 15-25 °C : 12 hours Between 2-8 °C : 5 days

		Between (-25)-(-15) °C : 4 weeks (when frozen once)
Differences		
Labeling	Labeled under ELITech	Labeled under Roche
Claim	9 of the 16 analytes	16 analytes

K. Standard/Guidance Document Referenced (if applicable):

None were referenced

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Not applicable

b. Linearity/assay reportable range:

Not applicable

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability

Components	Traceability
ALP	IFCC formulation (Tietz, 1983), manual measurement
ALT-GPT	ERM-AD454/IFCC
Gamma-GT	Original formulation (Persijn/v.d. Slik, 1976), manual measurement
LDH	IFCC formulation (Schumann, 2002), manual measurement

Abbreviations:

ERM: European Reference Material

IFCC = International Federation of Clinical Chemistry and Laboratory Medicine

Value Assignment:

EliTech performs verification on the provided calibrator values using Elitech's test systems on each calibrator lot. If the value provided by the manufacturer verifies, then it is used on the value sheet provided to the end user. When each new lot is received, the new lot is used to calibrate the system using the provided value. Then already-validated lots of control and an earlier lot of ELICAL are run as unknowns in quadruplicate on 2 Selectra analyzers, using 2 reagent lots, and 3 test vials per lot. If the result (mean of 48 tests) obtained is within the specification, +/-9% of the previously assigned bottle values, then the supplier's value is accepted.

Value assignment for the ELITROL I and ELITRIOL II control solutions was performed by quadruplicate runs on 2 Selectra analyzers, using 2 reagent lots, and 3 test vials per lot. The mean analyte value is calculated and a target value is assigned. The labeling states that obtained control solution values should fall within the specified range provided on lot-specific value sheets and that laboratories should establish appropriate quality control procedures when using this product for its intended use. The labeling also states that laboratories should recalibrate when reagents lots change, when quality control results fall out of range, and after a maintenance operation.

Stability:

Calibrator material is purchased from a commercial vendor (previously cleared under k033501) with no change to the content and the packaging except the labeling change. The sponsor claimed the following stability determined by the provider: ELICAL 2 is stable until the expiration date printed on the label when stored at 2-8°C prior to reconstitution. 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.

Control material is purchased from a commercial vendor (previously cleared under k041227) with no change to the content and the packaging except the labeling change. The sponsor claimed the following stability determined by the provider: Before reconstitution, the shelf-life of the ELiTech Clinical Systems Elitrol I and Elitrol II is 30 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.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.