

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

A. 510(k) Number:

k080404

B. Purpose for Submission:

New device

C. Measurand:

Calibrator and quality control materials for general chemistry analytes (see device description below).

D. Type of Test:

N/A

E. Applicant:

Medica Corporation

F. Proprietary and Established Names:

EasyQC- Chemistry

EasyQC- Electrolytes kit

EasyQC- Chemistry with Electrolytes

EasyCal- Chemistry Calibrator

EasyCal- CREA-U Calibrator

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJY	I	21 CFR 862.1660-Quality control material (assayed and unassayed)	Chemistry

JJR	I	21 CFR 862.1660-Quality control material (assayed and unassayed)	Chemistry
JIX	II	21 CFR 862.1150-Calibrator	Chemistry
JIT	II	21 CFR 862.1150-Calibrator	Chemistry

H. Intended Use:

1. Intended use(s):

See indications for use statement below.

2. Indication(s) for use:

MEDICA’s EasyQC – Chemistry, Levels A and B, is a quality control material for clinical chemistry intended for use in the MEDICA EasyRA Chemistry Analyzer to (estimate) test precision and to detect any potential systemic analytical deviations.

MEDICA’s Easy ElectroLytes kit is a quality control material for clinical chemistry intended for use in the MEDICA EasyRA Chemistry Analyzer to (estimate) test precision and to detect any potential systemic analytical deviations.

MEDICA’s EasyQC - Chemistry and Electrolytes, Levels A and B is a quality control material for clinical chemistry intended for use in the MEDICA EasyRA Chemistry Analyzer to (estimate) test precision and to detect any potential systemic analytical deviations.

MEDICA’s EasyCal - Multiconstituent Calibrator is intended for use in the MEDICA EasyRA Chemistry Analyzer to establish points of reference in the measurement of a number of analytes in human serum.

MEDICA CREA-U Cal is intended for use in the MEDICA EasyRA Chemistry Analyzer to establish points of reference in the measurement of Creatinine in urine.

3. Special conditions for use statement(s):

For in vitro diagnostic use; for prescription use

4. Special instrument requirements:

MEDICA EasyRA Chemistry Analyzer

I. Device Description:

The EasyQC Chemistry kit is a dual level lyophilized powder that is prepared from human serum. The human source material, from which this product was manufactured, has been tested at the single donor unit basis and found non-reactive for HBsAg, anti-HIV ½, anti-HCV and HIV-1 Ag. The kit contains the following analytes:

-Albumin	-Alk. Phosphatase
-ALT	-Amylase
-AST	- Bili-D
-Bili-T	-Calcium
-CO2	-Cholesterol
-Creatine Kinase	- Creatinine
-Iron	-GGT
-Glucose	
-HDL Cholesterol	-LDH
-Magnesium	-Phosphorus
-Total Protein	-Triglycerides
-Urea-N (BUN)	-Uric Acid

The EasyQC Chemistry and Electrolytes kit is a dual level lyophilized powder that is prepared from human serum. The human source material from which this product was manufactured has been tested at the single donor unit basis and found non-reactive for HBsAg, anti-HIV ½, anti-HCV and HIV-1 Ag. The kit contains the same analytes from the EasyQC Chemistry kit shown above, in addition to the following electrolytes:

- Sodium
- Potassium
- Chloride
- Lithium.

The EasyQC Electrolyte is a tri-level constituted solution containing salts, buffers, bovine albumin and preservatives. It does not contain human serum or human serum products. The analytes in this kit are sodium, potassium, chloride and lithium.

The EasyCal Multi-constituent Calibrator is provided in 3 mL vials of lyophilized, human serum powder. The human source material from which this product was manufactured has been tested at the single donor unit basis and found non-reactive for HBsAg, anti-HIV ½, anti-HCV and HIV-1 Ag. The kit contains the following analytes:

-Albumin	-Alk. Phosphatase
- Bili-D	-Bili-T
-Calcium	-CO2
-Cholesterol	- Creatinine

- Iron
- Glucose
- Phosphorus
- Triglycerides
- Uric Acid
- Magnesium
- Total Protein
- Urea-N (BUN)

The CREA-U Cal is a single 10 mL vial containing liquid creatinine prepared in 0.1 N Hydrochloric acid (for stability).

J. Substantial Equivalence Information:

1. Predicate device name(s):

DRY-Chemistry Lyophilized Control- k060322

Moni-trol Lyophilized chemistry controls- k960103

EasyLyte QC kit- k990971

Calibrate CH DRY-Chemistry calibrator- k060322

Creatine Urine Standard- k011126

2. Predicate K number(s):

k060322

k960103

k990971

k060322

k011126

3. Comparison with predicate:

The candidate devices contains the same analytes, has the same stability and traceability as the predicate devices.

The only two differences is that the k990971 (EasyLyte QC kit) contains two additional analytes that are not contained in this submission (iCa and pH).

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

None were reference.

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):*

Assignment of values for the analytes within the two calibrators, EasyCal Multiconstituent Calibrator and CREA-U Cal, were obtained from the master calibrator lot using 4 runs performed 2-4 EasyRA analyzers. Each new lot of calibrator material is tested in duplicate against the master calibrator lot in replicates of ten. Included in each run are duplicates of NIST or gravimetric standards (where NIST standards are not available) and two levels of QC material. The assigned values are based on the recoveries (and verification) of the master calibrator lot and the lot being assigned from the multiple runs on multiple device lots over several days.

Assignment of values for EasyQC Chemistry, EasyQC Electrolytes and, EasyQC Chemistry and Electrolytes control kits are determined from the mean of replicate assays from at least two laboratories using the reagents, calibrators, and controls available from the instrument manufacturer.

The master calibrators are traceable to NIST and other primary standards and are listed in the insert.

Stability for each device is shown in the table below:

Stability		
	Use-life store at 2-8C	Shelf-life at 2-8 C
EasyQC- Electrolytes	8 weeks	24 months

kit		
EasyQC- Chemistry	7 days (1 day for Co2 and 3 days for Total and Direct bilirubin)	36 months
Easy QC-Chemistry and electrolytes	5 days (1 day for CO2 and 3 days for Total and Direct bilirubin)	36 months
EasyCal- Chemistry Calibrator	5 days (1 day for CO2 and 3 days for total and direct bilirubin)	36 months
EasyCal- Creatinine Calibrator	18 months	18 months

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.