510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number: k041361

B. Purpose of Submission: Premarket Notification [510(k)] of intention to manufacture and market a Tri-Level Cardiac Control

C. Analyte: Multi Analyte Control:
Total CK, CK-MB activity, CK-MB mass, homocysteine, myoglobin, troponin I, and troponin T.

D. Type of Test: NA

E. Applicant: Randox Laboratories Ltd.

F. Proprietary and Established Names: Randox Tri-Level Cardiac Control

G. Regulatory Information:

1. Regulation section: 21 CFR §862.1660 Quality control material (assayed and unassayed)
2. Classification: Class I (reserved)
3. Product Code: JJY
4. Panel: 75

H. Intended Use:

1. Intended use(s):

This product is intended for *in vitro* diagnostic use in the quality control of Cardiac Markers on clinical chemistry and Immunoassay systems.

2. Indication(s) for use:

The Randox Laboratories Ltd. Tri-Level Cardiac Control (level I, II and III) are based on lyophilized human serum and have been developed for the control of both accuracy and precision in clinical chemistry application, specifically cardiac monitoring. The control materials are available at three constituent concentrations. Each level is available in a 1 mL final re-constituted volume.

3. Special condition for use statement(s): The Randox Laboratories Tri-Level Cardiac Controls should be used bu suitable qualified laboratory personnel under appropriate laboratory conditions.

4. Special instrument Requirements: The Randox Tri-Level Control can be used with a range of assays in a variety of Chemistry Analyzers. The specific assays and analyzers are listed in the package insert.

I. Device Description: The control contains human based lyophilized sera supplied at 3 levels. Human source material from which this product has been derived has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests. However, this material should be handled as though capable of transmitting infectious diseased and disposed accordingly.

J. Substantial Equivalence Information:

1. Predicate device name(s): Liquichek™ Cardiac Markers Control Levels 1, 2 and 3 by Bio-Rad

3. Predicate K number(s): k021498

4. Comparison with predicate:

Similarities		
Item	**Randox Tri Level Cardiac Control**	**Predicate: Liquichek Cardiac Markers LT K021498**
Intended use	Similar	Similar
Matrix	Human serum based	Human serum based
Number of Levels	3	3
Differences		
Item	**Randox Tri Level Cardiac Control**	**Liquichek Cardiac Markers LT K021498**
Analytes	Total CK, CK-MB activity, CK-MB mass, homocysteine, myoglobin, troponin I, troponin T	CK-MB, digitoxin, homocysteine, myoglobin, troponin I, troponin T
Form	Lyophilized	Liquid
Storage	Refrigerated 4 ºC	-20 ºC or colder

K. Standard/Guidance Document Referenced (if applicable):
None referenced.

L. Test Principle: NA

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:* NA

   b. Linearity/assay reportable range: NA

   c. Traceability (controls, calibrators, or method): The analytes are not traceable to Standards. Values are assigned from a consensus of a number of laboratories (4 to 43- depending on the analyte and method) and for CK-MB and myoglobin also from in house testing using Randox methods against a master lot of controls on a Hitachi 911 and AU400 (CK-MB) and a Hitachi 717 (myoglobin).

   Real time stability was performed and all values must meet the Randox acceptance criteria. Stability of reconstituted controls was also performed at 4 ºC and 25 ºC and the product labeled accordingly.

   c. Detection limit: NA

   d. Analytical specificity: NA

   e. Assay cut-off: NA

2. Comparison studies:

   a. Method comparison with predicate device: NA

   b. Matrix comparison: NA

3. Clinical studies:

   a. Clinical sensitivity: NA

   b. Clinical specificity: NA

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

4. Clinical cut-off: NA

5. Expected values/Reference range: NA

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantially equivalence decision.