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

A. 510(k) Number:

k061196

B. Purpose for Submission:

Clearance to market quality control material.

C. Measurand:

Control material for BNP, CKMB, CRP, digitoxin, homocysteine, myoglobin, pro-BNP, Tropinin I, and Troponin T.

D. Type of Test:

Quality control material

E. Applicant:

Microgenics Corp.

F. Proprietary and Established Names:

CardioImmune® XL Cardiac Marker Control

G. Regulatory Information:

1. Regulation section:

   21CFR 862.1660, Quality control material (assayed and unassayed)

2. Classification:

   Class I, reserved

3. Product code:

   JJY, multi-analyte controls, all kinds (assayed and unassayed)

4. Panel:

(75) Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   CardioImmune® XL Cardiac Marker Control is intended for use in the clinical laboratory as an assayed control serum for monitoring assay conditions in specific cardiac marker determinations.

3. Special conditions for use statement(s):

   For Prescription Use Only

4. Special instrument requirements:

   Not applicable

I. Device Description:

The CardioImmune®.XL Cardiac Marker Control is a three level control set used to for monitor instrument performance in specific cardiac marker determinations. The controls are prepared from a human serum matrix with the addition of various constituents. Analyte levels are adjusted by addition of pure chemicals, recombinant proteins, human tissue derived products and bodily fluids. The company provides this control material in a liquid, ready-to-use form.

Human source material is tested using FDA-accepted methods and found non-reactive for HCV, HIV-1/2, and HBsAg.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   MAS® CardioImmune® TL Liquid Assayed Cardiac Marker Control

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

   k043208

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Levels of Control	3	Same
Matrix	Prepared from human serum to which purified biochemical material (tissue extracts of human and animal origin), chemicals, drugs, preservatives, and stabilizers have been added.	Same
Product State at purchase	Frozen	Same
Stability Claim(frozen)	36 months at -20 °C	Same
Packaging	6 vials at one level, 3 ml/ vials; 2 vials at each level, 3 ml vials	Same
Common Analytes	CKMB, CRP, digitoxin, myoglobin, pro-BNP, Troponin I, Troponin T	Same

Differences		
Item	Device	Predicate
Additional Analytes	BNP, homocysteine	Not present

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

None referenced.

L. Test Principle:

Not applicable.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility:

   Not Applicable for a submission of this type.

   b. Linearity/assay reportable range:

   Not Applicable for a submission of this type.

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

The company assigns values to their controls by assaying 15 randomly selected vials over five days. Concentration assignments are made by comparison to NIST standards when available. When NIST standards are not available, the company uses a commercial standard. Assignments for particular platforms are determined through contracted 3rd party CLIA certified laboratories. For 3rd party assignment, the company uses 4 labs assaying points in duplicate over 2 days.

The company assessed the frozen shelf life of their device through accelerated aging studies. The company collected concentration measurements for representative samples stored at -20 °C, 4 °C, 23 °C, and 37 °C. Measurements were made every 6 days for up to 36 days. Concentrations were determined in triplicate. The company used this temperature data to estimate an energy of activation, E_a, for an Arrhenius model of stability. For analytes where no temperature dependent change in concentration was detected, the company used 20,000 cal/mol as an assigned activation energy.

The data supplied by the company supports their claim for a frozen shelf life of 36 months from the date of manufacture when stored at -20 °C. The company is conducting on-going real-time stability studies of material stored at -20 °C to further substantiate their stability claim.

The company assessed the thawed stability of their device when stored at 2-8 °C using real-time stability measurements. Material was withdrawn from refrigerated storage every 6 days for measurement. Concentrations were measured in triplicate.

The company employed a 2 tier acceptance criteria for determining the refrigerated shelf life for their device. For low level (Level I) control material, the company applied an absolute allowable concentration range. For intermediate and high (Levels II & III) material, the company applied used percentage change in concentration.

A summary of the company's findings:

Analyte	Specified Allowable Concentration Variations (%), Levels II & III	Specified Allowable Concentration Variations, Levels I	Days to Failure	Claimed Stability (Days)
BNP	±14%	±25 pg/ml	> 36	15
CKMB	±10%	±1.5 ng/ml	>36	15
CRP	±10%	±0.05 mg/ml	>36	30
Digitoxin	±10%	±2 ng/ml	>36	30
Homocysteine	±10%	±1.5 µ/ml	>36	30
Myoglobin	±10%	±1.5 ng/ml	>30	15

pro-BNP	±14%	±25 pg/ml	>36	15
Troponin I	±10%	±0.06 ng/ml	>36	30
Troponin T	±14%	±25 ng/ml	>36	15

The data supplied by the company supports their claims for an opened and unopened stability of 15 days for BNP, CKMB, myoglobin, pro-BNP, and Tropinin T when stored at 2–8°C.

The data supplied by the company supports their claims for an opened and unopened stability of 30 days for CRP, digitoxin, homocysteine, and Tropinin I when stored at 2–8°C.

d. Detection limit:

Not applicable for a device of this type.

e. Analytical specificity:

Not applicable for a device of this type.

f. Assay cut-off:

Not applicable for a device of this type.

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable for a device of this type.

b. Matrix comparison:

Not applicable for a device of this type.

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable for a device of this type.

b. Clinical specificity:

Not applicable for a device of this type.

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

Not applicable for a device of this type.

4. Clinical cut-off**:**

Not applicable for a device of this type.

5. Expected values/Reference range:

Not applicable for a device of this type.

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.