

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

A. 510(k) Number: K031873

B. Analyte: Control materials for CKMB, Myoglobin, Troponin I

C. Type of Test: NA

D. Applicant: i-STAT Corporation.

E. Proprietary and Established Names:

i-STAT Cardiac Markers Control Level 1

i-STAT Cardiac Markers Control Level 2

i-STAT Cardiac Markers Control Level 3

i-STAT Cardiac Markers Calibration Verification Control Set

F. Regulatory Information:

1. Regulation section:

21 CFR §862.1660 Quality control material (assayed and unassayed).

2. Classification: Class I

3. Product Code: JJX

4. Panel: 75

G. Intended Use:

1. Intended use(s):

The i-STAT Cardiac Markers Controls are used to verify the integrity of newly received i-STAT cTnI cartridges.

The i-STAT Cardiac Markers Calibration Verification Control Set is used to verify the accuracy of results over the measurement range of the i-STAT cTnI test.

2. Special condition for use statement(s): None

3. Special instrument Requirements: None

H. Device Description:

The i-STAT Cardiac Markers Controls are supplied in three levels packaged as six vials of one level per box with each vial containing 1 mL of control material. The three levels are each comprised of a different level of cardiac Troponin I, human creatinine kinase-MB isoform CK-MB, and myoglobin (all native forms) derived

from human cardiac material, prepared in human serum and preserved with sodium azide to inhibit microbial growth. The CK-MB and myoglobin are unassayed components in these materials. Only the cardiac troponin I (cTnI) values will be provided in the value assignment sheets for these products. The controls are provided in frozen liquid form and require no reconstitution.

The Cardiac Markers Calibration Verification Control Set is packaged as a tri-level set, comprised of two vials of each of three levels per box.

I. Substantial Equivalence Information:

1. Predicate device name(s):

More Diagnostics Cardiac Markers Control (#175)

2. Predicate K number(s): K982845

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Matrix	Human Serum	Human Serum
Preservative	Sodium Azide	Sodium Azide
Form	Frozen liquid	Frozen liquid
Differences		
Item	Device	Predicate
Analytes	CKMB (unassayed)	CKMB (assayed)
	Myoglobin (unassayed)	Myoglobin (assayed)
Vial	10 mL plastic vial with dropper-top	Plastic bulb
Fill volume	1 mL	300 uL

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

K. Test Principle: NA

L. 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 i-STAT Cardiac Marker Controls are each comprised of a different level of cardiac Troponin I, human creatinine kinase – MB isoform CK-

MB, and myoglobin (all native forms) derived from human cardiac material, and are prepared in human serum.

d. Detection limit: NA

e. Analytical specificity: NA

f. 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:

Approximate target values for troponin I are given in the table below. Lot-specific target values may differ slightly after value assignment.

cTnI	Range
Level 1	0.36-0.67 ng/mL
Level 2	1.42-2.64 ng/mL
Level 3	17.70-32.88 ng/mL

M. Conclusion:

Based on the information provided, I recommend that i-STAT Cardiac Markers Control Level 1, i-STAT Cardiac Markers Control Level 2, i-STAT Cardiac Markers Control Level 3, and i-STAT Cardiac Markers Calibration Verification Control Set are substantially equivalent to the currently marketed product.