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

A. 510(k) Number:

k112430

B. Purpose for Submission:

Minor labeling modification to a previously cleared device (k982071)

C. Measurand:

Lactic acid

D. Type of Test:

Quantitative, electrochemical biosensor (lactate oxidase)

E. Applicant:

Abbott Point of Care Inc.

F. Proprietary and Established Names:

i-STAT Lactate Test

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1450, Lactic acid test system

2. Classification:

   Class I, meets limitations of exemptions per 21 CFR 862.9 (c)(9)

3. Product code:

   KHP – Acid, Lactic, Enzyme Method

4. Panel:

   Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s): :
   See indications for use below

2. Indication(s) for use:

   The Lactate Acid Test is indicated for (1) the diagnosis and treatment of lactic acidosis in conjunction with measurements of blood acid/base status, (2) monitoring tissue hypoxia and strenuous physical exertion, and (3) diagnosis of hyperlactatemia.

   The Lactate Test, as part of the i-STAT System, is intended for the in vitro measurement of lactate in arterial, venous, or capillary whole blood.

3. Special conditions for use statement(s):
   For prescription use only

4. Special instrument requirements:
   i-STAT analyzer

I. Device Description:

Refer to k982071

J. Substantial Equivalence Information:

1. Predicate device name(s):

   iSTAT Lactate test

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

   k982071

3. Comparison with predicate:

   No changes were made to the device since k982071. Only minor labeling changes were made to the labeling in this submission.

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

No standards were referenced in the submission

L. Test Principle:

Lactate is measured amperometrically by conversion of lactate to pyruvate and hydrogen peroxide by lactate oxidase immobilized on a biosensor.

No changes have been made to the device technology in this submission. Refer to k982071

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. Precision/Reproducibility :

   Established in the original submission (k982071)

   b. Linearity/assay reportable range:

   Established in the original submission (k982071)

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

   Established in the original submission (k982071)

   d. Detection limit:

   Established in the original submission (k982071)

   e. Analytical specificity:

   Established in the original submission (k982071)

   f. Assay cut-off:

   Not Applicable

2. Comparison studies:

   a. Method comparison with predicate device:

   Established in the original submission (k982071)

   b. Matrix comparison:

   Established in the original submission (k982071)

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:
   Established in the original submission (k982071)

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.