

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

A. 510(k) Number:

k103195

B. Purpose for Submission:

Adding wireless functionality to the i-STAT Analyzer (k001387) to communicate testing results to a PC

C. Manufacturer and Instrument Name:

Abbott Point of Care, Inc. i-STAT 1 Wireless Analyzer

D. Type of Test or Tests Performed:

Hematocrit, glucose, blood urea nitrogen, sodium, potassium, chloride, ionized calcium, blood gases (oxygen, carbon dioxide, and pH), creatinine, lactate, activated clotting time, prothrombin time, bicarbonate/carbon dioxide, troponin, creatine phosphokinase, and beta natriuretic peptide.

E. System Descriptions:

1. Device Description:

The i-STAT 1 Wireless Analyzer incorporates a radio-frequency transceiver (IEEE 802.11 b/g protocol), also known as a wireless module. This design modification provides a new method for users to transmit patient data to a Data Manager. It does not replace the existing method for transmitting data that uses an Infra-Red (IR) transceiver in the i-STAT Analyzer together with accessories that provide a wired connection to a Data Manager. The capability of the Wireless Analyzer to transmit test results and information by Radio Frequency (RF) transmission is an option that the user may choose but it is not required for the Wireless analyzer to fulfill the intended use or to meet the indications for use. (Which method is used to transmit data is selected by the user.)

The operation of the wireless function during the User Interface application of the JAMS firmware is temporally distinct from the operation of the Measurement Cycle application when the i-STAT test cartridges are being processed and tests are being conducted. The control of the i-STAT 1 Wireless Analyzer assures that the RF module is not powered during the measurement cycle. All operations during the measurement cycle are identical in the predicate i-STAT Analyzer and in the Wireless Analyzer.

2. Principles of Operation:

Once the Measurement Cycle within an i-STAT test cartridge has been completed, the test results are stored in the analyzer and are displayed on the Analyzer LCD display where they are available for use by the medical professional. At this point, the User Interface Cycle begins during which the stored test results can be transmitted to a Data Manager via the IR transceiver or

RF transmission at the convenience of the user.

3. Modes of Operation:

This submission only pertains to a wireless mode of data transmission being added to a previously cleared i-STAT Analyzer (k001387). The Analyzer software and the data transmission to a PC via the IR transceiver have been reviewed in that previous submission.

4. Specimen Identification:

See k001387.

5. Specimen Sampling and Handling:

See k001387.

6. Calibration:

See k001387.

7. Quality Control:

See k001387.

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes or No

F. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JGS	II	21 CFR 862.1665 Sodium test system	Chemistry
CEM	II	21 CFR 862.1600 Potassium test system	Chemistry
CGZ	II	21 CFR 862.1170 Chloride test system	Chemistry
CDS	II	21 CFR 862.1770 Urea Nitrogen test system	Chemistry
JPI	II	21 CFR 864.6400 Hematocrit measuring device	Hematology
JFP	II	21 CFR 862.1145 Calcium test system	Chemistry
CHL	II	21 CFR 862.1120 Blood gases (PCO ₂ , PO ₂) and blood pH test system	Chemistry
CGL	II	21 CFR 862.1225 Creatinine test system	Chemistry

KHP	II	21 CFR 862.1450 Lactic acid test system	Chemistry
JBP	II	21 CFR 864.7140 Activated whole blood clotting time test	Hematology
GJS	II	21 CFR 864.7750 Prothrombin time test	Hematology
JFL	II	21 CFR 862.1160 Bicarbonate/carbon dioxide test system	Chemistry
MMI	II	21 CFR 862.1215 Creatine phosphokinase/creatine kinase or isoenzymes test system	Chemistry
MYT	II	21 CFR 862.1215 Creatine phosphokinase/creatine kinase or isoenzymes test system	Chemistry
NBC	II	21 CFR 862.1117 B-type natriuretic peptide test system	Chemistry
CGA	II	21 CFR 862.1345 Glucose test system	Chemistry
JJX	I	21 CFR 862.1660 Quality control material	Chemistry

G. Intended Use:

1. Indication(s) for Use:

The i-STAT 1 Wireless Analyzer is used by trained medical professionals for running a variety of clinical chemistry tests and test panels contained in i-STAT test cartridges. These tests include hematocrit, glucose, blood urea nitrogen, sodium, potassium, chloride, ionized calcium, blood gases (oxygen, carbon dioxide, and pH), creatinine, lactate, activated clotting time, prothrombin time, bicarbonate/carbon dioxide, troponin, creatine phosphokinase, and beta natriuretic peptide.

- Sodium measurements are used for monitoring electrolyte imbalances.
- Potassium measurements are used for diagnosis and monitoring of diseases and clinical conditions that manifest high and low Potassium levels.
- Chloride measurements are primarily used in the diagnosis, monitoring and treatment of electrolyte and metabolic disorders including but not limited to cystic fibrosis, diabetic acidosis and hydration disorders.
- Glucose measurements are used in the diagnosis, monitoring and treatment of carbohydrate metabolism disorders including but not limited to diabetes mellitus, neonatal hypoglycemia, and idiopathic hypoglycemia, and of pancreatic islet cell carcinoma.

- Hematocrit measurements can aid in the determination and monitoring of normal or abnormal total red cell volume status including but not limited to conditions such as anemia and erythrocytosis and blood loss related to trauma and surgery.
- Blood urea nitrogen measurements are used for the diagnosis, monitoring and treatment of certain renal and metabolic diseases.
- Ionized calcium measurements are used in the diagnosis, monitoring and treatment of conditions including but not limited to parathyroid disease, a variety of bone diseases, chronic renal disease and tetany and disturbances related to surgical and intensive care.
- pH, pCO₂ and pO₂ measurements are used in the diagnosis, monitoring and treatment of respiratory disturbances and metabolic and respiratory based acid-base disturbances.
- Creatinine measurements are used in the diagnosis and treatment of renal diseases, in monitoring renal dialysis, and as a calculation basis for measuring other urine analytes.
- The i-STAT lactate test is useful 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 i-STAT Kaolin Activated Clotting Time (ACT) test is an in vitro diagnostic test used to monitor high-dose heparin anticoagulation frequently associated with cardiovascular surgery.
- The i-STAT PT, a prothrombin time test, is useful in monitoring patients receiving oral anticoagulation therapy such as Coumadin or warfarin.
- Bicarbonate/carbon dioxide measurements are used in the diagnosis and treatment of numerous potentially serious disorders associated with changes in body acid-base balance.
- The i-STAT Cardiac Troponin I (cTnI) test is an in vitro diagnostic test for the quantitative measurement of cardiac troponin I in whole blood or plasma. Measurements of cardiac troponin I are used in the diagnosis and treatment of myocardial infarction and as an aid in the risk stratification of patients with acute coronary syndromes with respect to their relative risk of mortality.
- The i-STAT CKMB test is an in vitro diagnostic test for the quantitative measurement of creatinine kinase MB mass in whole blood or plasma samples. CK-MB measurements can be used as an aid in the diagnosis and treatment of myocardial infarction (MI).
- The i-STAT BNP test is an in vitro diagnostic test for the quantitative measurement of B-Type Natriuretic Peptide (BNP) in whole blood or plasma samples using EDTA as the anticoagulant. BNP measurements can be used as an aid in the diagnosis and assessment of the severity of congestive heart failure.
- The i-STAT Celite ACT test is useful for monitoring patients receiving heparin for treatment of pulmonary embolism or venous thrombosis, and for monitoring anticoagulation therapy in patients undergoing medical procedures such as catheterization, cardiac surgery, surgery, organ transplant and dialysis

2. Special Conditions for Use Statement(s):

Prescription use only.

H. Substantial Equivalence Information:

1. Predicate Device Name(s) and 510(k) numbers:

i-STAT Analyzer (Model 300), k001387

2. Comparison with Predicate Device:

Similarities		
Item	Predicate device (k001387)	Proposed device
Indications for use	The i-STAT Analyzer is used by trained medical professionals for running a variety of clinical chemistry tests and test panels contained in i-STAT test cartridges.	Same
Cartridge use	Compatible with i-STAT cartridges	Same
Control of the transmission of data	JAMS software	Same
Software updates	Via short range IR	Same

Differences		
Item	Predicate device (k001387)	Proposed device
Analytes	Hematocrit, glucose, blood urea nitrogen, sodium, potassium, chloride, ionized calcium, blood gases (oxygen, carbon dioxide, and pH, creatinine, lactate and activated clotting time.	Hematocrit, glucose, blood urea nitrogen, sodium, potassium, chloride, ionized calcium, blood gases (oxygen, carbon dioxide, and pH), creatinine, lactate, activated clotting time, prothrombin time (originally cleared under k020355), bicarbonate/carbon dioxide (k053110), troponin (k031739), creatine phosphokinase (k051433), and beta natriuretic peptide (k053597).

Wireless test result transmission	Not available	Incorporates a wireless module based upon the IEEE 802.11 b/g communication protocol (“Wi-Fi”) to be used to transmit test results to a Data Manager
Data transmission option	IR Port	IP Port or Wireless Module
Analyzer appearance	Beige	Blue; a “wireless” symbol is present on the bezel

I. Special Control/Guidance Document Referenced (if applicable):

- IEC 61326-2-6: *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment*
- IEC 61326-1: *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements*
- UL 61010-1:2nd Ed. 07/04 Rev 07/2/05 *Safety of Electrical Equipment for Measurement, Control and Laboratory Use*
- FCC: 47 CFR Part 15.247:2005 (Subpart C)
- FCC: 47 CFR Part 15.247:2006 (Subpart C)
- FCC: 47 CFR Part 15 Subpart B: Class A

J. Performance Characteristics:

1. Analytical Performance:

a. *Accuracy:*

The measurement cycle activities performed within the i-STAT cartridges are identical in the i-STAT 1 Analyzer and in the Wireless Analyzer, therefore accuracy studies were not performed.

b. *Precision/Reproducibility:*

The measurement cycle activities performed within the i-STAT cartridges are identical in the i-STAT 1 Analyzer and in the Wireless Analyzer, therefore new precision studies were not performed.

c. *Linearity:*

The measurement cycle activities performed within the i-STAT cartridges are identical in the i-STAT 1 Analyzer and in the Wireless Analyzer, therefore new linearity studies were not performed.

d. Carryover:

The measurement cycle activities performed within the i-STAT cartridges are identical in the i-STAT 1 Analyzer and in the Wireless Analyzer, therefore new carryover studies were not performed.

e. Interfering Substances:

The measurement cycle activities performed within the i-STAT cartridges are identical in the i-STAT 1 Analyzer and in the Wireless Analyzer, therefore new studies to evaluate potential interfering substances were not performed.

2. Other Supportive Instrument Performance Data Not Covered Above:

The following testing was performed to evaluate the wireless function:

1. Testing that demonstrated that i-STAT patient results are transmitted successfully to the pertinent data fields on the receiving computer for all i-STAT tests that can be used with the i-STAT wireless analyzer.
2. Testing that demonstrated that multiple i-STAT 1 Wireless Analyzers can transmit results to a computer simultaneously without corruption of the data or patient mix-up.
3. Testing that demonstrated that the wireless module is not powered during the measurement cycle
4. Testing that demonstrated that the wireless module is off if the analyzer is off.

The integrity of transmitted data is assured by the use of:

- A cyclic redundancy check (CRC) of data that is the same as that used in the predicate i-STAT 1 Analyzer (Model 300). Approximately 99.9985% of any corrupted data will be detected by the CRC.
- A TCP/IP protocol that is the same as used in the predicate device.
- The IEEE 802.11 protocol that is inherent in the operation of the healthcare facility's wireless router.

K. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

L. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.