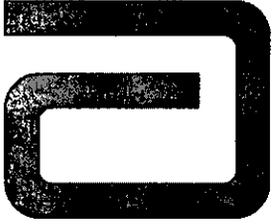


Abbott Point of Care Inc.
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K103195
FEB - 8 2011



510(k) Summary
i-STAT 1 Wireless Analyzer

This summary of the 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1900 and CFR 807.92.

The assigned 510(k) number is: K103195

Summary prepared on: Tuesday, February 1, 2011

Submitted by:

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Establishment Registration Number: 2245578

Identification of Device:

Device Name: i-STAT 1[®] Wireless Analyzer
Proprietary/Trade Name: i-STAT 1[®] Wireless Analyzer
Common Name: i-STAT 1[®] Analyzer, i-STAT Analyzer, handheld

Device Classification:

Class	Name	Regulation Number	Product Code	Panel
II	Glucose Oxidase, Glucose.	862.1345	CGA	Clinical Chemistry
II	Test, Natriuretic Peptide.	862.1117	NBC	Clinical Chemistry
II	Bicarbonate/Carbon Dioxide Test System.	862.1160	JFL	Clinical Chemistry
II	Biosensor, Immunoassay, CPK or Isoenzymes.	862.1215	MYT	Clinical Chemistry
II	Immunoassay Method, Troponin Subunit.	862.1215	MMI	Clinical Chemistry
II	Test, Time, Prothrombin.	864.7750	GJS	Hematology
II	Activated Whole Blood Clotting Time.	864.7140	JBP	Hematology
II	Acid, Lactic, Enzymatic Method.	862.1450	KHP	Clinical Chemistry
II	Electrode, Ion Based, Enzymatic, Creatinine.	862.1225	CGL	Clinical Chemistry
II	Electrode Measurement, Blood-Gases (pCO ₂ , pO ₂) And Blood pH	862.1120	CHL	Clinical Chemistry

Class	Name	Regulation Number	Product Code	Panel
II	Electrode, Ion Specific, Calcium.	862.1145	JFP	Clinical Chemistry
II	Electrode, Ion Specific, Sodium.	862.1665	JGS	Clinical Chemistry
II	Electrode, Ion Specific, Potassium.	862.1600	CEM	Clinical Chemistry
II	Electrode, Ion Specific, Chloride.	862.1700	CGZ	Clinical Chemistry
II	Electrode, Ion Specific, Urea.	862.1770	CDS	Clinical Chemistry
II	Hematocrit	864.6400	JPI	Hematology

Identification of the Predicate Device:

Device Name: i-STAT 1[®] Analyzer

Indications 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 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

The i-STAT¹ 1 Wireless Analyzer (Model 300W) is a variant of the predicate i-STAT 1 Analyzer (Model 300) (K001387) and it provides an additional and alternate method for communication of data to a facility database. The i-STAT 1 Analyzer together with single use i-STAT Cartridges is a complete analytical system that can be used at the point of patient care.

The primary purpose of the analyzer is to run a variety of tests contained in disposable, single-use i-STAT Cartridges. The enabling technology for the i-STAT system is in the microfabricated electrochemical sensors located in the disposable cartridges. The functions related to testing patient samples using this technology are not affected by the addition of the wireless capability.

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.

The principle differences between the i-STAT 1 Wireless Analyzer and the predicate i-STAT 1 Analyzer are:

- The i-STAT 1 Wireless Analyzer 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 Manager².
- The i-STAT 1 Wireless Analyzer does not support the measurement of glucose test strips.

This application describes and provides information and background related to the incorporation of the wireless module into the i-STAT 1 Analyzer. 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

¹ i-STAT is a registered trademark of Abbott Point of Care Inc., Princeton, NJ.

² For the purposes of this application, the term Data Manager will mean either a facility computer that has i-STAT Central Data Station application or a facility server that has i-STAT/DE application installed in it. Data Manager provides a link to transfer of information from the i-STAT System to a hospital-maintained database.

i-STAT 1 Analyzer together with accessories that provide a wired connection to a Data Manager. Which method is used to transmit data is selected by the user. Data Manager includes a server-based or personal computer-based utility that facilitates transmission of results from an i-STAT System to a data base maintained by a medical facility.

The operation of the wireless function is temporally distinct from the operation of the measurement cycle. 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 1 Analyzer and in the Wireless Analyzer. Data is provided that shows the power supply is off during the measurement cycle and also during power down of the analyzer. The measurement cycle activities are identical in the i-STAT 1 Analyzer and in the Wireless Analyzer. Therefore no cartridge tests to compare the test performance of the Wireless Analyzer to the predicate i-STAT 1 Analyzer was carried out.

This 510(k) application establishes the i-STAT 1 Wireless Analyzer to be substantially equivalent to the i-STAT 1 Analyzer. The design modification does not create significant risks and particular attention has been paid to those concerns and issues highlighted in the "Radio-Frequency Wireless Technology in Medical Devices Draft Guidance" FDA January 3, 2007.

The use of the industry standard IEEE 802.11 provides a high degree of confidence to the users that the coexistence of the i-STAT 1 Wireless Analyzer within a medical facility is predictable, easily managed, and provides a high degree of assurance that there is a low risk that intentional electromagnetic radiation from the Wireless Analyzer will result in unacceptable interference with other medical equipment in the immediate vicinity.

There is an acceptable, low risk that the radio frequency emissions will result in thermal injury to a patient or user. This is based on Specific Absorption Rate tests conducted by the supplier of the radio frequency module.

The following are the same in the i-STAT 1 Analyzer and the i-STAT 1 Wireless Analyzer.

- Both models are compatible with all i-STAT Cartridges.
- Both models may be used in the same facility locations and by the same medical professionals.
- The indications for use for each individual test apply regardless of which Analyzer is used to run the tests.
- The basic design and the materials used are the same in both models.
- Neither model transmits real-time physiologic information or critical information such as alarms to remote monitoring stations.
- The JAMS software provides for the control of the transmission of data in both models.
- In the former, the software directs the transmission using the IR port. In the Wireless Analyzer the software allows the user to direct the transmission using either the wireless module or the IR port.
- Both models use Transmission Control Protocol/Internet Protocol (TCP/IP) and a Cyclic Redundancy Check (CRC) protocol to ensure that acceptance of corrupted data is improbable. Approximately 99.9985% of any corrupted data will be detected by the CRC.
- Both models conform to the laboratory electromagnetic compatibility (EMC) standard IEC 61326-2-6 for unintentional emissions and susceptibility.

- Both models, in combination with alternating current-powered accessories, conform to the electrical safety requirements of UL 61010-1.

The following are different in the i-STAT 1 Wireless Analyzer compared to the i-STAT 1 Analyzer.

- The Wireless Analyzer incorporates a radio-frequency transceiver (IEEE 802.11 b/g protocol) that has been certified as an unlimited module by a Telecommunications Certification Board and accordingly bears a Federal Communications Commission identification number.
- The wireless communication will rely upon the IEEE 802.11 infrastructure that is already ubiquitous in medical facilities.
- The wireless module is not powered during the measurement cycle.
- A software utility, used to configure the wireless communication system at installation, is provided as a CD-ROM.
- The color is blue (the predicate device is beige) and the word “wireless” is on the bezel.
- In the Wireless Analyzer, the ability to run a glucose test strip is disabled.

The following table summarizes features and functions that are in the Wireless Analyzer but are not present in the predicate i-STAT 1 Analyzer.

Feature or Function	Wireless Analyzer
Data integrity protection (wireless).	IEEE 802.11 b/g
Components required for wireless function.	RF module. Isolated power supply.
Device Label	FCC ID Number included.
Wireless Configuration Utility	Provided as CD-ROM.
Ability to run MediSense Glucose strips.	Disabled
Appearance	Blue keypad and bezel with “WIRELESS” label.
Battery Life	Shortened up to 30%



Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Abbott Point of Care Inc.
c/o Larry W. Krasley
Regulatory Scientist
400 College Road East
Princeton, NJ 08540

FEB 08 2011

Re: k103195
Trade Name: i-STAT 1 Wireless Analyzer
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Codes: CGA, CDS, CEM, CGL, CGZ, CHL, GJS, JBP, JFL, JFP, JGS,
JPI, MMI, MYT, NBC, KHP
Dated: December 21, 2010
Received: December 23, 2010

Dear Mr. Krasley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

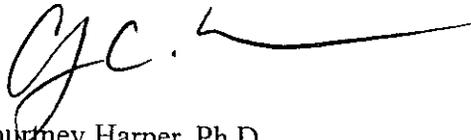
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'CHC', followed by a long horizontal line extending to the right.

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): k103195

Device Name: i-STAT 1 Wireless Analyzer

Indications for Use:

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- 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 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.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k103195

Indications for Use Form

510(k) Number (if known): k103195

Device Name: i-STAT 1 Wireless Analyzer

Indications for Use: (continued)

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- The i-STAT PT, a prothrombin time test, is useful in monitory patients receiving oral anticoagulation therapy such as Coumadin or warfarin.
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- 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

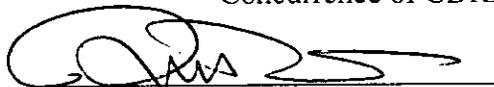
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



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510(k) k103195