



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

December 14, 2015

GI Logic Inc  
% Albert Rego  
Regulatory Consultant  
Albert Rego, Phd  
27001 La Paz Road  
Suite 312/314  
Mission Viejo, California 92691

Re: K150782  
Trade/Device Name: Abstats Gateway  
Regulation Number: 21 CFR 870.1875  
Regulation Name: Stethoscope  
Regulatory Class: Class II  
Product Code: DQD  
Dated: November 4, 2015  
Received: November 9, 2015

Dear Albert Rego:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150782

Device Name

Abstats Gateway

Indications for Use (Describe)

The AbStats Gateway is a compact device with integrated sensor interfaces and embedded computing system (stethoscope) that in conjunction with external sensors constitutes the AbStats system. The AbStats system external sensors are placed on the abdomen and identify the vibratory signals associated with digestive processes. This device should be used under the direction of a licensed healthcare practitioner when it is required to determine this patient digestive state. The device has not been tested for and it is not intended for pediatric use.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary  
(As required by 21 CFR 807.92)

**Submitted By:** GI Logic®, Inc.  
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Pasadena, CA 91106-2996  
USA

**Contact Person:** Albert Rego Ph.D., Inc.  
27001 La Paz Road, Suite 312  
Mission Viejo, CA 92691  
Contact: Albert Rego  
Phone: (949) 770-8710

**Date Prepared:** March, 2015

**Trade Name:** AbStats® Gateway

**Common Name:** Electronic Stethoscope

**Classification Name:** Electronic Stethoscope (21 CFR 870.1875)

**Regulatory Class:** Class II

**Product Code:** DQD

**Predicate Device:** RNK PCP-USB Stethoscope (K132560)

**Device Description:**

The AbStats Gateway is a compact device with integrated sensor interfaces and embedded computing system (stethoscope) that in conjunction with external sensors constitutes the AbStats system. The AbStats system external sensors are placed on the abdomen and identify the vibratory signals associated with digestive processes.

The AbStats Gateway system is a compact, rapidly deployable unit that is comfortable for subjects and convenient in application. The AbStats Gateway sensor includes a standard microelectronic microphone for measurement of vibration acoustic signals. The components in patient contact are disposable, avoiding the need for cleaning and disinfection. The only material in direct contact with the subject is standard, FDA-approved 3M Tegaderm wound bandage adhesive material.

The AbStats Gateway sensor includes a system that provides usage assurance of proper application to the patient. The AbStats Gateway sensor includes both an electret microphone and a compact vibration source (based on the principle of standard signaling vibration sources in consumer pager and



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smartphone systems). This small electronic vibration device emits a short duration (50 millisecond length) signal each 2 minutes during usage and alternately from each sensor.

This low amplitude and low frequency (less than 1 kHz) vibration signal is not detectable by the subject. It propagates between the two AbStats sensors where it is detected by the AbStats device and provides direct assurance of proper application of the two sensors.

The AbStats Gateway sensor includes fine, flexible cables that connect to the AbStats Gateway. The AbStats Gateway is a low voltage device that is similar in size to a tablet computer. The AbStats Gateway monitors the AbStats sensor signals and provides a measurement of intestinal motility with a Motility Rate. The rate is calculated based on rate of arrival of acoustic events detected by AbStats sensors.

#### Indications for Use:

The AbStats Gateway is a compact device with integrated sensor interfaces and embedded computing system (stethoscope) that in conjunction with external sensors constitutes the AbStats system. The AbStats system external sensors are placed on the abdomen and identify the vibratory signals associated with digestive processes. This device should be used under the direction of a licensed healthcare practitioner when it is required to determine this patient digestive state. The device has not been tested for and it is not intended for pediatric use.

#### IDENTIFICATION OF LEGALLY MARKETED PREDICATE DEVICE

The predicate device used for direct comparison of and the determination of substantial equivalence is:

PCP-USB Stethoscope (K132560)

The identification of this predicate device is in accordance with ensuring the Agency that this premarket notification is consistent with the currently approved (predicate) device, and meets all expectations of form, fit, function, and safety.

#### COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The comparison of features and operation principles between AbStats Gateway from GI Logic, Inc., and PCP-USB Stethoscope (K132560) from RNK Products is listed as follows:



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| Parameter           | AbStats Gateway   | PCP-USB Stethoscope<br>K132560   | Comparison               |
|---------------------|---|--|--------------------------|
| Indications for Use | <p>The AbStats Gateway is a compact device with integrated sensor interfaces and embedded computing system (stethoscope) that in conjunction with external sensors constitutes the AbStats system. The AbStats system external sensors are placed on the abdomen and identify the vibratory signals associated with digestive processes. This device should be used under the direction of a licensed healthcare practitioner when it is required to determine this patient digestive state. The device has not been tested for and it is not intended for pediatric use.</p> | <p>The PCP-USB Stethoscope is intended to transmit auscultation sound data, whereby a clinician at one location on an IP network can listen to the auscultation sounds of a patient at a different location on the IP network with the signal carried on an IP connection between the two locations.</p> | Substantially Equivalent |



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| Parameter   | AbStats Gateway                             | PCP-USB Stethoscope K132560                       | Comparison  |
|---|---|---|---|
| Number of Sensors   | 2   | 1   | Different Number - Substantially Equivalent Functionality                             |
| Sensor size (mm) Active Area  | 30 mm x 20 mm<br>400 mm <sup>2</sup>        | Approximately 30 mm x 20mm<br>400 mm <sup>2</sup> | Substantially Equivalent  |
| Sensor Technology   | Standard Electrical Microphone              | Standard Electrical Microphone                    | Substantially Equivalent  |
| System Technology   | Sensor data signal processing and computing | Sensor data signal processing and computing       | Substantially Equivalent  |
| Interface to PC   | None required (no PC Interface)             | USB Interface                                     | Interface is different but each unit provides Substantially Equivalent Functionality  |
| Data Box Connection to PC   | None required (no PC Interface)             | USB Interface                                     | Interface is different but each unit provides Substantially Equivalent Functionality  |
| Power Supply  | 5V USB Power Source                         | 5V USB Power Source                               | Substantially Equivalent  |
| Sensor Cable Length (m)   | 2.0 m                                       | Approximately 0.5 m                               | Cable Length is different - each unit provides Substantially Equivalent Functionality |
| IEC6060 1-1:2005 3rd Edition Medical Electrical Equipment Part 1: General Requirement for Safety and to EN60601-1-2, 2007/03, | Conformance                                 | Conformance                                       | Equivalent  |



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| Parameter   | AbStats Gateway   | PCP-USB Stethoscope K132560   | Comparison               |
|---|---|---|--------------------------|
| EMC Requirements for Safety, 2. Collateral Standard - Electromagnetic Compatibility Requirements and Tests. | Conformance   | Conformance   | Equivalent               |
| Immunity Requirements for Medical Electrical Equipment Part 1: General                                      | Conformance   | Conformance   | Equivalent               |
| Software  | The AbStats software processes audio signals for display and presentation to the user.  | The PCP-USB Stethoscope software processes audio signals for display and presentation to the user.<br><br>The PCP-USB Stethoscope software provides additional data transport capability to remote users. | Substantially Equivalent |
| Biocompatibility  | Device use the same materials the predicate that a patient or clinician might touch, the biocompatibility analysis is the same. | Devices use the same materials that a patient or clinician might touch, the biocompatibility analysis is the same.  | Substantially Equivalent |
| Auscultation Performance Tests: Bench Testing and Clinicians  | Passed/Conformance  | Passed/Conformance  | Equivalent               |

**Biocompatibility Testing:**

There is no biocompatibility testing for the AbStats device or sensors, in that there is not direct patient contact except through the use of commercially available dermal adhesive dressings.

**Electrical Safety and electromagnetic compatibility (EMC):**

Electrical safety and EMC testing were conducted on the AbStats device, consisting of the device with sensors. The system complies with 1EC6060 1-1:2005 3rd Edition Medical Electrical Equipment Part 1: General Requirement for Safety and to EN60601-1-2, 2007/03, EMC Requirements for Safety,



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2. Collateral Standard – Electromagnetic Compatibility Requirements and Tests. Immunity Requirements for Medical Electrical Equipment Part 1: General.

Software Verification and Validation Testing:

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software contained in Medical Devices. The software for this device is considered as "moderate" level of concern.

Animal Study:

The AbStats Gateway was determined not to require animal performance testing due to clinical trial results (proof of function studies).

Clinical Study:

The AbStats Gateway was determined not to need Clinical Evaluations due to clinical trial results (proof of function studies). The IRB Approved Clinical Trial results are given in the following public domain reference:

Brennan M R Spiegel, Marc Kaneshiro, Marcia M Russell, Anne Lin, Anish Patel, Vartan C Tashjian, Vincent Zegarski, Digvijay Singh, Samuel E Cohen, Mark W Reid, Cynthia B Whitman, Jennifer Talley, Bibiana M Martinez, William Kaiser, "Validation of an acoustic gastrointestinal surveillance biosensor for postoperative ileus", J Gastrointest Surg 2014 Oct 5;18(10):1795-803

Functional Study (Proof of Function):

The results indicated that the AbStats Gateway successfully met all design requirements.

| Title of Test Report          | Report Number |
|-------------------------------|---------------|
| AbStats Operation Test Report | TR-001        |



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A summary of the final report is provided below:

| Test Step | Test Description  | Observed System Response   | Test Pass (P) or Fail (F) |
|-----------|---|--|---------------------------|
| 1         | System Boot after application of system power.                                      | System Boot observed with proper screen annunciator Welcome Message displayed.   | P                         |
| 2         | Test of Time Zone Setting   | Time Zone Setting Message appeared correctly.  | P                         |
| 3         | Test of Time Zone Continue State  | Time Zone Accepted and Displayed followed by continuation to next state.   | P                         |
| 4         | Test of Time Zone Setting State   | Time Zone Entry Accepted and Displayed followed by continuation to next state. Multiple tests confirm operation for all Time Zones.  | P                         |
| 5         | Start of New or Continued Study Choice Display                                      | Start of New or Continued Study Choice was displayed correctly.  | P                         |
| 6         | Sensor Search Sequence Test with Sensor Disconnect State                            | Sensors are disconnected from Simulator. AbStats System continues to indicate search for sensors at display correctly.   | P                         |
| 7         | Sensor Search Sequence Test with Sensor Connect State                               | Sensors are Connected at Simulator. AbStats System indicates proper detection of sensors at display correctly.   | P                         |
| 8         | Sensor Recording Cycle Test.  | AbStats system enters Recording Cycle correctly after Sensor Search State.   | P                         |
| 9         | Sensor Recording Start with Sensor Disconnect                                       | AbStats System detects Sensor Disconnect state correctly.  | P                         |
| 10        | Sensor Recording Start with Sensor Disconnect                                       | AbStats System Display Message Indicating Sensor Disconnect state correctly. Acquired data removed correctly.  | P                         |
| 11        | Sensor Recording Start with Sensor Disconnect with Usage Assurance Test (UAT) Loop. | AbStats System Display Message Indicating Sensor Disconnect state correctly. Acquired data removed correctly. AbStats System remains in Usage Assurance Test (UAT) recording loop correctly. | P                         |
| 12        | Sensor Recording Start with Sensor Connect  | AbStats System acquires signals from Simulator, computes signal count by Analysis, and displays signal count with correct signal count value.  | P                         |



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#### Conclusions:

Since the comparison of bench testing to clinical outcomes is still not well understood for this type of device, clinical testing was required to support substantial equivalence in the form of functional evaluation and proof of function. The non-clinical data support the safety and effectiveness of the device and the hardware and software verification and validation demonstrate that the AbStats Gateway device should perform as intended in the specified use conditions. The clinical data demonstrate that the AbStats Gateway device functions in a manner comparable to the predicate device that is currently marketed for the same intended use.

The AbStats Gateway device utilizes the same technologies as the predicate device and is considered to be substantially equivalent to the predicate device in form, fit, function, safety and efficacy.