February 28, 2019

Sensible Medical Innovations Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K180479
Trade/Device Name: ReDS System
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance Plethysmograph
Regulatory Class: Class II
Product Code: DSB
Dated: February 25, 2019
Received: February 25, 2019

Dear Janice Hogan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen C. Browning -S5

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180479

Device Name
ReDS System

Indications for Use *(Describe)*

The ReDS System is intended for use by qualified healthcare practitioners, under the direction of a physician, in hospitals, hospital-type facilities and home environments, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.
The ReDS System is indicated for patients:

- With fluid management problems
- Taking diuretic medication
- Living with heart failure
- Recovering from a coronary artery disease-related event

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.

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510(K) SUMMARY

UPDATE DATE : FEBRUARY 9, 2019

ReDS System V2.7

510(k) Number K180479

Applicant's Name:

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Device Trade Name:

ReDS System

Common/Classification Name:

Impedance plethysmograph

Classification:

FDA has classified impedance plethysmographs as Class II devices (product code DSB, 21 CFR 870.2770), and they are reviewed by the Cardiovascular panel.

Predicate Devices:

- ReDS Wearable System V2.6 (K150095)

Indications for Use:

The ReDS System is intended for use by qualified health care practitioners, under the direction of a physician, in hospitals, hospital-type facilities and home environments, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications.

The ReDS System is indicated for patients:

- With fluid management problems
- Taking diuretic medication
- Living with heart failure
- Recovering from a coronary artery disease-related event

Device Description:

The ReDS System ("ReDS" or "ReDS System") is a non-invasive thoracic base wave impedance monitor that provides measurement of patient lung fluid content. ReDS™ technology measures wave impedance of biological tissues. Low power electromagnetic (EM) signals are emitted into the body, and intercepted by sensors on the body. The wave impedance is a function of the distributed tissue conductivity and capacitance properties, and is representative of tissue fluid content.

The system consists of a Sensor Unit connected to a bedside console, as well as a cloud application. The Sensor Unit encases two sensors and an attachment mechanism. The Bedside Console is an enclosure housing the electronic modules, an embedded computer and a touch-screen display. The device software provides the management of the device as well as analysis of the measured signals, graphic display of readings, reporting, and communications functionality to enable remote patient monitoring.

Technological Characteristics:

The ReDS System's technological characteristics are substantially equivalent to those of its predicate device, i.e., the first generation ReDS System V2.6. Both devices are non-invasive, prescription use, transportable bedside devices indicated for use in hospital and hospital-like environments by healthcare providers. Same as the predicate, ReDS V2.7 uses non-invasive measurements of impedance characteristics to assess the amount of fluid in tissue. Both devices use sensors placed on the user's body and measurement initiation through a graphical user interface. ReDS V2.7 sensors are located in a clip-like sensor unit, whereas the predicate device use sensors embedded in the wearable vest. The minor differences noted above between ReDS V2.7 and the ReDs V2.6 predicate device

do not raise new types of safety and effectiveness questions. These differences have been assessed in bench, human factors, and clinical testing. Results established that the ReDS System V2.7 performs as intended and is substantially equivalent to its predicate device.

Performance Data:

ReDS System V2.7 was evaluated in non-clinical and clinical testing. Results demonstrated that the device meets specifications and supported substantial equivalence to the predicate device. The device is not provided sterile and does not require end user sterilization.

Biocompatibility

ISO 10993 testing demonstrated biocompatibility of the device materials. Cytotoxicity (ISO 10993-5), skin irritation (ISO 10993-10), and sensitization (ISO 10993-10) testing demonstrated all passing results, supporting the biocompatibility of the device for its intended use.

Software

Software validation and verification testing was conducted for the ReDS System software. Results demonstrated that the software was appropriate for release. The software hazard analysis was performed in accordance with ISO 14971:2007.

Electrical Safety and Electromagnetic Compatibility

Electrical safety and electromagnetic compatibility testing were conducted. Results demonstrated that the system complies with the applicable testing standards (IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, IEC 60601-1-6, and IEC 62366).

Bench Testing

Bench testing, demonstrating substantial equivalence to the predicate device, provided verification and validation of mechanical durability, packaging and transportation, quality feedback mechanisms, and cleaning and disinfection. Usability testing was also conducted to validate use of the system by the intended professional users. All performance testing passed according to defined acceptance criteria, demonstrating that the device performs as expected.

Clinical Data

Clinical data was provided to further assess the ReDS System V2.7 equivalency to ReDS System V2.6. Results showed equivalent performance of the two ReDS System generations. The equivalency presented in the clinical setting was consistent with the findings of the nonclinical studies. No device-related adverse events were reported.

Conclusion:

ReDS System V2.7 has the same intended use and similar indications for use, technological characteristics, and principles of operation as the predicate device, ReDS System V2.6. Any minor differences between the two generation of devices do not raise any new questions of safety or effectiveness. Performance tests, confirm that these differences do not adversely impact safety or performance. In summary, the conclusions from the non-clinical and clinical tests demonstrate that ReDS System V2.7 is as safe, as effective, and performs as well as or better than the legally marketed predicate device, ReDS System V2.6.

Substantial Equivalence Comparison Table

Criteria	ReDS V2.6 (As Cleared In K150095)	ReDS V2.7 (K180479)
Manufacturer	Sensible Medical Innovations Ltd.	Sensible Medical Innovations Ltd.
K Number	K150095	K180479
Product Code	DSB	DSB
Classification	Class II	Class II
Product Classification/ Common Name	Plethysmograph/Fluid Status Monitor	Same
Indications for Use	ReDS is intended for use by qualified health care practitioners and by patients, under the direction of a physician, in hospitals, hospital-type facilities and home environment, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications. ReDS is indicated for patients: ◊ With fluid management problems ◊ Taking diuretic medication ◊ Living with Heart Failure ◊ Recovering from Coronary Artery Disease related event	The ReDS System is intended for use by qualified health care practitioners, under the direction of a physician, in hospitals, hospital-type facilities and home environments, for the non-invasive monitoring and management of patients with fluid management problems in a variety of medically accepted clinical applications. The ReDS System is indicated for patients: ◊ With fluid management problems ◊ Taking diuretic medication ◊ Living with heart failure ◊ Recovering from a coronary artery disease-related event

Criteria	ReDS V2.6 (As Cleared In K150095)	ReDS V2.7 (K180479)
Range of Patient Anatomies (Height, BMI)	◊ The system is suitable for both male and female patients with a body mass index of 22 to 36 and a height of between 155 cm (5' 1'') to 190 cm (6' 3'').	◊ The system is suitable for both male and female patients with a body mass index of 22 to 36 and a height between 155 cm (5' 1'') to 195 cm (6' 5''). ◊ Patients within the height range having a BMI of 36 to 38 can use the system if their chest size ruler value (as measured by the unit) is 39 or less.
Rx Device	Yes	Yes
Power Source	AC powered	Same
Technology	Induced electromagnetic fields are used to measure wave impedance of the thorax.	Same
Energy Type	Electromagnetic fields at 1-2 Ghz	Same
Device Display Parameter (Fluid)	Measurement of fluid status by: ◊ Base impedance in Ohm (Ω) units (70–150Ω) or ◊ Volume percent (%) units (15-60%)	Measurement of fluid status by: ◊ Volume percent (%) units (15-60%) (base impedance option no longer presented)
Sensor Attachment Configuration	◊ 2 non-touch sensors embedded in a wearable vest attached to the patient thorax on the front and back of chest ◊ Vest is adjustable for patient dimensions	◊ 2 non-touch sensors embedded in a clip-like sensor unit attached to the patient thorax on the front and back of chest

Criteria	ReDS V2.6 (As Cleared In K150095)	ReDS V2.7 (K180479)
	◊ Bedside console connected to the patient sensor vest via a cable	◊ Unit is adjustable for patient dimensions ◊ Bedside console connected to the clip-like sensor unit via a cable
Main System Components - Electronics	RF Signal generator and analyzer	Same with added WiFi connectivity
Software	V2.6 Software	V2.6 Software with the following main additions: ◊ User interface providing Sensor Unit use instructions ◊ Multi-patient management with anonymized ID option ◊ Historical readings screen
Cloud Application	V2.6 SensiCloud application	V2.6 SensiCloud application with the following main additional features: ◊ User interface enhancements ◊ HCP option to set thresholds range and receive out of range notices. ◊ Patient's measurements graph UI improvements (e.g. a green zone was added on the graph marking the center range) ◊ Task management indicators for administrative users
User Interface	10" Touch screen graphical user interface and display	Same
Algorithm	◊ Calculation of thorax impedance from measured signals	◊ Same with a stricter signal quality assessment mechanism

Criteria	ReDS V2.6 (As Cleared In K150095)	ReDS V2.7 (K180479)
	◊ Conversion of impedance measurements to present fluid content in volume percentage units ◊ Assessment of signal quality	
Mode of Use	◊ Intermittent use ◊ Application on a single patient	◊ Intermittent use ◊ Application on single and multiple patient