August 3, 2018

Smart Solutions Technologies SL
% Nandini Murthy
Regulatory Consultant
ENEM Consulting, LLC
556 Lowell Street
Lexington, Massachusetts 02420

Re: K173461
Trade/Device Name: Nuubo System
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical magnetic tape recorder
Regulatory Class: Class II
Product Code: DSH, DQK
Dated: July 31, 2018
Received: August 1, 2018

Dear Nandini Murthy:

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,

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K173461

Device Name

Nuubo System™

Indications for Use *(Describe)*

The Nuubo System is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, presyncope, syncope, fatigue, or anxiety.

The Nuubo system continuously records and stores ECG and activity data for up to 30 days at a time. The Nuubo System detects arrhythmias at the end of the monitoring period upon download of the ECG data. The Nuubo System is Rx use device

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

SECTION 5

510(k) SUMMARY – K173461

Submitter Name: Smart Solutions Technologies SL

Submitter Address: Calle Toronga 21, Local 1, Madrid 28015, Spain

Contact Person: Daniel Llorca

Phone Number: (+34) 609 882 563

Submission Correspondent: Nandini Murthy

Phone Number: (781) 710-5378

Date Prepared: August 3, 2018

Device Trade Name: Nuubo System

Device Common Name: ECG Recorder, Arrhythmia Detection

Classification Name: Medical Magnetic Tape Recorder

Classification regulation: 21 CFR 870.2800, Product Code DSH, DQK

Predicate Device: ZioPatch (K143513)

Reference devices: Monebo (K062282)
my Patch sl (K163535)
Cardiobelt (K063044)
Accuheart (K043361)
Preventice (K151188)

Classification Name: Medical Magnetic Tape Recorder

Classification regulation: 21 CFR 870.2800, Product Code DSH, DQK, DSI

Device Description:

The Nuubo System, developed by Smart Solutions Technologies (SST), is a wearable device designed for ambulatory recording electrocardiogram (ECG) up to 30 days. The system is composed of 3 main components:

- Nuubo30 – The Nuubo30 wearable is a single patient textile like a chest-belt that contains 4 textile electrodes in the inner side that are used for sensing patient´s ECG. The patient places the inner side of the textile in direct contact to the skin in

the chest region, and an electroconductive media is placed in between the electrodes and the skin to sense the patient's ECG. The textile has an electrical and mechanical snap connector to plug the Recorder.

- NuuboREC - The Nuubo recorder is a small, lightweight device that records ECG continuously. The device records 2 Leads of ECG data up to 30 days. The device also records data from a 3-axis accelerometer located inside the device. The patient can activate the button while wearing the product to mark a symptom. To start and stop the recording the user will press the on/off button. The data is stored into a micro SD memory card.
- Nuubo Leonardo – The Leonardo Software is installed on a computer where the patient´s ECG data stored in the recorder will be downloaded for subsequent analysis and report. The Leonardo software also prepares the recorder for new patients, enabling the user to erase the data from previous patients and synchronizing time and data.

Indications for Use:

The Nuubo System is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, presyncope, syncope, fatigue, or anxiety.

The Nuubo system continuously records and stores ECG and activity data for up to 30 days at a time. The Nuubo System detects arrhythmias at the end of the monitoring period upon download of the ECG data. The Nuubo System is Rx use device.

Rationale for Substantial Equivalence:

The table below is a comparison of the Indications for use of the Nuubo against the predicate device.

Substantial Equivalence Comparison: Indications for use

Indications	**Nuubo** **K173461**	**ZioPatch** **K143513**
Indications for use	The Nuubo System is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety. The Nuubo system continuously records and stores ECG and activity data for upto 30 days at a time. The Nuubo System detects arrhythmias at the end of the monitoring period upon download of the ECG data. The Nuubo System is a Rx use device.	Prescription-only, single-patient-use, continuously recording ECG monitor that can be worn up to 14 days. It is indicated for use on patients who may be asymptomatic or who may suffer from transient symptoms such as palpitations, shortness of breath, dizziness, light-headedness, pre-syncope, syncope, fatigue, or anxiety.

Substantial Equivalence: Indications for use

The Indications for Use is the same as the predicate device.

Indications for Use Comparison:
Nuubo and the predicate device are both prescription devices, intended for use in recording ECG in the ambulatory environment. The Nuubo includes a proprietary algorithm (Leonardo) that can be used to download and analyze for arrhythmias following the recording. This application is similar to the ZioPatch (K143513**)**, which has a similar post-recording ECG analysis feature. The workflow of the Nuubo intended use and system features is equivalent to that of the predicate, in that both systems include a sensor, a recorder that are used to record ECG signals in the ambulatory environment. At the end of the monitoring period, the recorded data is analyzed via a proprietary arrhythmia detection algorithm. In the case of the ZIO, a technician reviews it before it goes to a Clinician for review/editing/reporting. In the case of the Nuubo system, the recorded data is analyzed via the Leonardo in the Clinician's office by the QHP (there is no interim technician review service), then a Clinician or trained technician should review the events detected prior to generating a report. The two systems are substantially equivalent by indications for use, workflow/intended use and technology/components.

Substantial Equivalence: Technology

Comparison of Nuubo Features to Predicate Device

Characteristics	**Nuubo**	**ZioPatch**
Product Code	DQK, DSH	DXH, DQK, DSH
Number of leads	Two leads	One lead
Monitor Multiple Parameters	Yes (ECG and motion)	Yes (ECG, HR)
Event detection	Patient triggered, during 30 day use	Patient triggered, during14 day use
Data Transmission	Bluetooth only to verify connection (onboarding) Data transmission at the end of the monitoring period	Data transmission at the end of the monitoring period
Arrhythmia detection	Yes, at end of monitoring period	Yes, at end of monitoring period

The Nuubo and the predicate device:

- Include an ECG recording feature
- Monitor multiple parameters
- Include 1-2 leads
- Allow patients to record events
- Are used in the ambulatory environment for ECG recording
- Store recorded parameters on the local hardware (recorder)
- Include proprietary arrhythmia detection capability in a standalone software package

Differences:

The Nuubo has minor differences from the predicate.

The Nuubo System is intended for use up to 30 days, while the ZIO monitors for up to 14 days. Further the Nuubo monitors for motion (ZIO monitors for HR) and has 2 leads (versus one lead for ZIO). However, there are other cardiovascular ECG monitors that are used in the same intended use environment and include the same features as Nuubo system.

Reference device Preventice (K151188) includes features like monitoring up to 30 days, monitoring for motion, has two leads, requires that the patient charge the device every 12 hours and that electrodes be replaced every 3 days. Note that the intended use of the Preventice is also ECG monitoring with arrhythmia detection.

Another difference between the Nuubo and the predicate devices is the battery used to power the device. Nuubo uses a rechargeable Lithium ion polymer battery using a micro-USB plug to connect the power adapter, instead the predicate devices use a non rechargeable battery. Ziopatch uses a 2 connected disposable batteries of 3V 225 mAh. However there is another cardiac monitor reference device (my Patch sl, K163535) with similar feature of using a micro-USB to charge the battery.

Another difference between the Nuubo and the predicate devices is the form factor of the ECG electrodes/leads as worn on the body. However, there are other cardiac monitoring reference devices with similar features. Both the Cardiobelt (K063044) and Accuheart (K043361) have electrodes in a wearable belt.

Performance Data:
Preclinical software/algorithm testing, biocompatibility, shipping/packaging and usability study results validate Nuubo System towards its proposed intended use, and supports substantial equivalence to the predicate.

The following are the referenced standards during design and development of Nuubo:

- ISO 15223-1:2016, Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied
- ISO 14971:2007, Medical Devices Risk Management – Part 1: Application of Risk Analysis to Medical Devices
- IEC 62304:2006, Medical Device Software – Software Life Cycle Process
- ANSI/AAMI EC12 “Disposable ECG Electrodes”
- ANSI/AAMI/ISO 10993-1 “Biological evaluation of medical devices -- Part 1: Evaluation and testing”
- IEC 62366-1:2015, titled Medical devices – Part 1: Application of usability engineering to medical devices, published by the International Electrotechnical Commission.
- AAMI HE 75:2009, titled Human Factors Engineering – Design of Medical Devices, Section 9 – Usability Testing, published by the Association for the Advancement of Medical Instrumentation.
- IEC 60601-1-2 4th edition Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests.

- Recognition Number 19-4: AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, c1:2009/(r)2012 and a2:2010/(r)2012 (consolidated text) medical electrical equipment - part 1: general requirements for basic safety and essential performance (IEC 60601-1:2005, mod). (General II (ES/EMC))
- IEC 60601-1-11: 2015 Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- ANSI/ AAMI/ IEC 60601-2-47: 2012 Medical Electrical Equipment -- Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- IEC 60601-1:2012 (Edition 3.1): Test of defibrillation protection

Nuubo30 was tested to the ISO10993 standards, including cytotoxicity, irritation, sensitization and material characterization per ISO 10993-18.

The Transport Simulation test according to ASTM D 4169 DC 13 of

(i) Nuubo shipping box, containing products Nuubo30, NuuboREC and Nuubo Leonardo

(ii) of a shipping bag containing the Nuubo Patient box

and subsequent visual inspection (ASTM F 1886/F 1886M: Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection; 2016) were successfully completed.

The Nuubo System was subject to, and successfully completed the EMI/EMC/Electrical safety test requirements per IEC60601. Although Nuubo System labeling contraindicates use during cardiac defibrillation. In a likely emergency situation, if a responder attempts to defibrillate a patient without removing the Nuubo System, the Nuubo System design mitigates potential thermal risk.

The Nuubo system was also subject to the following preclinical tests:

- System safety testing
  - Software verification and validation
- ECG Performance testing
- Wireless transmission data quality and wireless coexistence testing

Summative usability testing was completed, demonstrating that 98.4% participants did not encounter any difficulties associated with a risk for potential of serious harm (critical tasks). The results show that the Nuubo System can be used by the patient, caregiver and healthcare professional per the labeled instructions for use.

The Nuubo Arrhythmia detection algorithm was tested per requirements of AAMI/IEC60601-2-47. To validate the arrhythmia detection algorithms were used three public databases and one private database. The public databases were MIT-BIH, AHA and MITAF. The Private Database comprised of 90 ECG registries of 58 patients.

Registries were selected to contain all the arrhythmias detected by our algorithm. All the data used from the study was anonymized, keeping only the ECG raw data recorded on the device, age and sex of the patient. The database was annotated using experienced medical professionals, using prospectively defined guidelines, consistent with US medical practice.

The next list shows the arrhythmias detected by the Nuubo arrhythmia algorithms.

Algorithm functionality	Detection criteria
Beat detection	Nuubo Arrhythmia Algorithm beat detector relies on the amplitude of the signal. It is a modified Tompkins detector that has an adaptive threshold of beat detection above 0.2mV, which is the minimum value to detect a beat.
Heart rate measurement	Heart rate is calculated by averaging the RR of the beats contained in non-overlapped windows of 10 seconds.
Normal beats classification	A beat with a morphology similar to the predominant normal morphologic family or contained in it that is considered to be not premature.
Supraventricular beats classification	A beat with a morphology similar to the predominant normal morphologic family, or contained in it that is considered to be premature. Prematurity is defined as having a RR interval 80% shorter than the RR average of the 4 preceding beats.
Ventricular beats classification	A beat with morphology different than the predominant normal morphologic family that fits with ventricular criteria of width, premature ratio or dissimilarity.
Atrial Fibrillation	Irregular rhythm longer than 30 seconds
Isolated Ventricular beat	One Ventricular beat [V] isolated surrounded by non-ventricular beats not contained in a bigeminy or trigeminy sequence.
Ventricular Pair	Two consecutive Ventricular beats [VV] surrounded by non-ventricular beats.
Ventricular Run	Three or more consecutive Ventricular beats [VVV].
Ventricular Bigeminy	At least one sequence of [Ventricular / Normal or Non Classified / Ventricular] beats [VNV].
Ventricular Trigeminy	At least one sequence of [Ventricular / Normal or Non-Classified / Normal or Non-Classified / Ventricular] beats [VNNV].

Algorithm functionality	Detection criteria
Isolated Supraventricular beat	One Supraventricular beat [S] isolated surrounded by non-supraventricular beats.
Supraventricular Pair	Two consecutive Supraventricular beats [SS] surrounded by non-supraventricular beats.
Supraventricular Run	Three or more consecutive Supraventricular beats [SSS].
Pauses	A RR Interval longer than 2000ms.
Tachycardia	A rhythm faster than 100 bpm longer than 10 beats of any type.
Bradycardia	A rhythm slower than 50 bpm longer than 10 seconds with beats of any type.

The results obtained validate the Nuubo Arrhythmia Algorithms and prove equivalence to Monebo Automated ECG Analysis And Interpretation Software Library, version 3.0 [manufacturer Monebo Technologies, 510(k) number K062282]. The predicate ZioPatch 510(k) K091075 referenced the Monebo for purposes of comparison, therefore, the Monebo was chosen for this arrhythmia performance. All results are comparable to the results claimed by Monebo.

The Nuubo Arrhythmia Detection Algorithm is not intended to replace the Clinician review of signals. The software menu prompts the Clinician or trained technician to review events prior to generating a report

Conclusion:
Nuubo System has similar indications statements as the predicate device. Both devices are used for ECG monitoring by patients in the ambulatory environment.

Preclinical software/algorithm testing, biocompatibility, shipping/packaging, usability, EMI/EMC/Electrical safety and ECG electrode test results validate Nuubo System towards its proposed intended use. These above-referenced study results, along with a comparison of the indications for use and technological features between the Nuubo and the predicate device, supports a finding of substantial equivalence. Based on arrhythmia validation testing and the AAMI/ IEC 60601-2-47 report, the arrhythmia detection algorithm used by the Nuubo Leonardo software application complies with the standard requirements as well as the performance requirements established for it.

Therefore, Nuubo System is substantially equivalent to the predicate device.