August 1, 2023

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

Re: K231620
Trade/Device Name: Nuubo Smart
Regulation Number: 21 CFR 870.2800
Regulation Name: Medical Magnetic Tape Recorder
Regulatory Class: Class II
Product Code: DSH, DQK, DXH
Dated: May 31, 2023
Received: June 2, 2023

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Shruti N. Mistry -S

Jennifer Shih
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231620

Device Name
Nuubo Smart

Indications for Use *(Describe)*
The Nuubo Smart 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 Smart continuously records and stores ECG and activity data for up to 30 days at a time. The Nuubo Smart detects arrhythmias at the end of each monitoring day upon download of the ECG data. The Nuubo Smart 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

Submitter Name:	Smart Solutions Technologies SL
Submitter Address:	Paseo de la Castellena 200 Madrid Madrid 28046 ES
Company Contact Person:	Borja Gonzalvez
Company contact Ph:	(+34) 961 344 497
Submission Correspondent:	Nandini Murthy
Date Prepared:	31 May 2023
Device Trade Name:	Nuubo Smart
Device Common Name:	ECG and arrhythmia detection monitor
Classification code, name:	21 CFR 870.2800, Code DSH, Recorder, Magnetic Tape, Medical 21 CFR 870.1425, Code DQK, Computer, Diagnostic, Programmable 21 CFR 870.2800, Code DXH
Predicate Devices:	Nuubo System K173461 SEEQTM System K133701
Reference Devices:	Bodyguardian System K121197 Stealth System S300 K162503 MoMe Kardia Wireless Ambulatory ECG Monitoring And Detection System K160064
Intended use:	The Nuubo Smart developed by Smart Solutions Technologies S.L. (SST), is a wearable device designed for ambulatory recording and transmitting electrocardiogram (ECG) up to 30 days. The intended use is identical to the predicate Nuubo system.
Device Description:	Nuubo Smart is composed of the following main components:

Nuubo30 (wearable) - The Nuubo30 is the wearable box that contains one Nuubo30 textile unit, ECG conductive cream, patient instructions and washing bag. Each textile can be used for 30 days.

NuuboREC (recorder). 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 Dock - The Nuubo Dock is the element for downloading the data from the NuuboREC and uploads that data to the Nuubo Cloud. It consists of a plastic stand with a smartphone attached to it and a microUSB port where the NuuboREC is connected for recharge and data download. The smartphone is a single-purpose device that is intended to be always connected to the dock. The dock is intended to be connected to an outlet in the patient's home with the charger provided. The dock allows to charge the NuuboREC device, and during this charging, it downloads the data from the NuuboREC device into the smartphone. The smartphone is software restricted and can only run the Nuubo Dock App that transmits and receives data from the Nuubo Cloud.

Leonardo Smart - Is used for downloading, analysis, visualization and report of the ECG-data stored by the recorder device and for managing the recorder device. The new version Leonardo Smart allows a clinical professional previously authenticated in the platform, to download and review signals recorded by the NuuboREC device which have been uploaded using Nuubo Dock.

Indications for Use:

The Nuubo Smart 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 Smart continuously records and stores ECG and activity data for up to 30 days at a time. The Nuubo Smart detects arrhythmias at the end of each

monitoring day upon download of the ECG data. The Nuubo Smart is Rx use device.

Rationale for Substantial Equivalence:

Substantial Equivalence Comparison: Indications for use

Indications	Nuubo Smart	Nuubo System K173461	SEEQ™ System K133701
Indications for use	The Nuubo Smart 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 Smart continuously records and stores ECG and activity data for up to 30 days at a time. The Nuubo Smart detects arrhythmias at the end of each monitoring day upon download of the ECG data. The Nuubo Smart is Rx use device	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.	The NUVANT (SEEQ) System is intended to continuously measure, record and periodically transmit physiological data. The System is indicated for those patients who require monitoring for the detection of non-lethal cardiac arrhythmias such as, but not limited to, supraventricular tachycardias (e.g. atria] fibrillation, atrial flutter, paroxysmal SVTs), ventricular ectopy, bradyarrhythmias and conduction disorders. The NUVANT System monitors, derives and displays: * ECG * Heart Rate

The Indications for Use statement for the Nuubo Smart differs slightly from that of the primary predicate device to address automatically detected events daily and not at the end of the monitoring; however, these differences do not alter the intended use of the device. Collectively, the subject device has the same intended use in cardiac arrhythmia diagnostics as the two predicate devices.

The Indications for Use statement for the Nuubo Smart differs slightly from the secondary predicate device (SEEQ). Both systems are indicated for the same population and detection of non-lethal cardiac arrhythmias, but the indications of use of Nuubo Smart are stated in terms of symptoms referred by the patient instead of arrhythmias detected. The SEEQ System refers in the manual that, based on the indications, the system could be used in "patients with symptoms such as chest pain, syncope, light-headedness or near syncope, vertigo, dizziness, fall, palpitations, transient ischemic episodes, and dyspnea (shortness of breath) that might be due to cardiac arrhythmias", which are nearly the same as Nuubo Smart. The type of arrhythmias detected are the same in both systems.

Differences in the proposed Indications for Use statement does not affect the safety and effectiveness profile of the subject device relative to the predicate devices. Therefore, the subject device can be considered substantially equivalent to the predicate devices.

Substantial Equivalence: Technology

Comparison of Nuubo Features to Predicate Device

Characteristics	Nuubo Smart	Nuubo System (primary) K173461	Nuubo Smart vs Nuubo System Comparison	SEEQ™ System K133701	Nuubo Smart vs SEEQ System Comparison
Product Code	DSH, DQK, DXH	DSH, DQK	Similar	DSI	Similar
Number of leads	Two leads	Two leads	Same	One lead	Similar. Nuubo Smart has one more ECG lead
Parameters	ECG and motion	ECG and motion	Same	ECG	Similar
Event detection	Patient triggered or automatically by arrhythmia detection. Automatic Algorithm analysis every time the patient uploads data.	Patient triggered or automatically by arrhythmia detection Algorithm at the end of the monitoring period.	Similar	Manually by patient or automatically by arrhythmia detection algorithm	Similar.

Characteristics	Nuubo Smart	Nuubo System (primary) K173461	Nuubo Smart vs Nuubo System Comparison	SEEQ™ System K133701	Nuubo Smart vs SEEQ System Comparison
Full Disclosure available	Yes	Yes	Same	Yes	Same
Monitoring Data Transmission	Cellular transmission.	None. Data downloaded through microSD card (USB) at the end of monitoring	Different. Nuubo Smart includes cellular transmission through the Nuubo Dock when the patient recharges the device.	Bluetooth and cellular transmission.	Similar
Duration of use	Up to 30 days	Up to 30 days	Same	Up to 30 days	Same
Key System components	1. Nuubo30 (wearable sensor) 2. NuuboREC (recorder) 3. Nuubo Smart App (transmitter) 4. Nuubo Leonardo Smart (analysis)	1. Nuubo30 (wearable sensor) 2. NuuboREC (recorder) 3. Nuubo Leonardo (Software)	Similar. Nuubo Smart includes a Dock and an app to transmit the data periodically	1. SEEQ™ MCT Wearable Sensor (Piix) 2. SEEQ™ MCT Transmitter (zLink) 3. Software	Same. Key components are the same (a sensor, a transmitter and a software)
Arrhythmias detected	- Atrial Fibrillation - Pauses - Tachycardia - Bradycardia	- Atrial Fibrillation - Pauses - Tachycardia - Bradycardia	Same	- Tachycardia - Bradycardia - Pauses - Atrial Fibrillation	Similar. Arrhythmias detected are nearly the same.

Characteristics	Nuubo Smart	Nuubo System (primary) K173461	Nuubo Smart vs Nuubo System Comparison	SEEQ™ System K133701	Nuubo Smart vs SEEQ System Comparison
	- Supraventricular Run - Ventricular Run - Ventricular Ectopy - Supraventricular Ectopy	- Supraventricular Run - Ventricular Run - Ventricular Ectopy - Supraventricular Ectopy		- Ventricular Tachycardia / Ventricular Fibrillation	
Electrode type	Textile electrode	Textile Electrode	Same	Patch with Ag/AgCl "wet" electrode assembly	Different. Validation of textile electrode, comparison and Substantial Equivalence to a wet Ag/AgCl electrode was already submitted in Nuubo System (K173561)

The Nuubo and the predicate devices are similar with following features:

- Include an ECG recording feature
- Monitor additional parameters like motion (primary predicate)
- Include 1-2 leads
- Use same electrode type and sensor assembly (Nuubo30 from primary predicate device)
- Allow patients to record events
- Are used in the ambulatory environment for ECG recording
- Store recorded parameters on the local hardware (recorder) (primary predicate)
- Send data periodically to be reviewed (secondary predicate)

- Create reports with relevant findings periodically and at the end of the monitoring.
- Include proprietary arrhythmia detection with same type of arrhythmias

Both systems are validated for applicable performance features like biocompatibility, packaging/shipping, EMI/EMC/Electrical safety and validation of the arrhythmia detection algorithm.

Differences:
The Indications for Use statement for the Nuubo Smart differs slightly from that of the primary predicate device to address automatically detected events daily and not at the end of the monitoring; however, these differences do not alter the intended use of the device. Collectively, the subject device has the same intended use in cardiac arrhythmia diagnostics as the two predicate devices. Differences in the proposed Indications for Use statement are not critical to the intended use of the device, nor do they affect the safety and effectiveness of the subject device relative to the predicate devices. The only difference with respect to detection of arrhythmias is that the secondary predicate device detects Ventricular Fibrillation. This is a potentially lethal arrhythmia which needs immediate medical attention and therefore it is not needed to be detected in a non-attended ambulatory monitoring technology like Nuubo Smart where there are no real time alarms or events. The electrodes used for recording the ECG are different between the Nuubo Smart (textile electrode) and the secondary predicate device (wet Ag/Agcl electrode). The validation of the textile electrodes was submitted in Nuubo System submission (K173561), where substantial equivalence was granted against a very similar patch with wet Ag/Agcl electrode assembly. Therefore, the subject device can be considered substantially equivalent to the predicate devices.

Another difference between the Nuubo and the predicate devices is that the data is sent to the cloud via a commercial phone with an app (secondary predicate uses a specific device for this purpose). However, there is another cardiac monitor reference device, Bodyguardian System (K121197), which similar to Nuubo Smart, uses a commercial phone as an accessory to enable cellular communications and use a Android App to get protected access to the cloud.

Another difference between the Nuubo and the predicate devices is the way the data is downloaded from the recording device. However, there is another cardiac monitor reference device, Stealth System S300 (K162503), which similar to Nuubo Smart, uses a custom dock as a cable/connector to enable communications between the recording device and the software to analyze the data.

Another difference between the Nuubo and the predicate devices is the technology to store and process signals in the cloud. However, there is another cardiac monitor reference device, MoMe Kardia Wireless Ambulatory ECG Monitoring and Detection System (K160064), which similar to Nuubo Smart, stores the information and analyzes the data via the embedded algorithm in the cloud and, when indicated, data identified by the algorithm is flagged for physician review.

Declaration of Conformity to Standards:
Preclinical software/algorithm testing, biocompatibility, shipping/packaging and usability study results validate Nuubo Smart towards its proposed intended use, and supports substantial equivalence to the predicate, and conformance to applicable harmonized standards.

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 62133 Safety Requirements for portable secondary cells, which applies for the lithium polymer battery

Summary of Bench testing

Test	Results
Section 14: Shipping and packaging tests	The Transport Simulation test according to ASTM D 7386 TS-4 of Nuubo Smart box, the Transport Simulation test according to ASTM D 4169 DC 13 of 4 Nuubo Smart units 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.

Test	Results
Section 15: Biocompatibility	The Nuubo Smart uses the same textile belt technology as Nuubo System (K173461), which was subject to the ISO10993 standards, including cytotoxicity, irritation, sensitization and material characterization per ISO 10993-18
Section 16 – Software testing	Software passed all Unit Testing and System Verification and Validation Testing to show it met all requirements
	The Nuubo Leonardo Arrhythmia detection algorithm (same as Nuubo System K173461) was tested per requirements of IEC60601-2-47, and showed a QRS Sensitivity and QRS Positive predictivity of over 99% against the MIT-BIH database, and over 97% against the AHA database
Section 17 – EMI/EMC	The Nuubo Smart system successfully completed the EMI/EMC/Electrical safety test requirements per IEC60601.
Section 18 – Bench studies	Wearable and recorder verification and validation testing to confirm it met all requirements (design input), including for battery performance for the proposed up to 30 days of use

Summary of Clinical Testing:

Section 20: Summative usability testing was completed demonstrating that patients and caregivers did not encounter any difficulties associated with a risk for potential of serious harm (critical tasks).

Conclusion:
The design, function, specifications, and performance of the Nuubo Smart are similar to the identified legally marketed predicate and reference devices. Further, the Nuubo Smart is compliant with applicable harmonized standards, and where any differences relative to the predicate have been verified and validated. Therefore, the subject device is substantially equivalent to the existing legally marketed devices.