March 28, 2025

Makani Science, Inc.
% Thomas Kroenke
Principal Consultant
Speed To Market, Inc.
PO Box 3018
Nederland, Colorado 80466

Re: K233953
Trade/Device Name: Makani Science™ Respiration Monitoring System
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: Class II
Product Code: BZQ
Dated: March 7, 2025
Received: March 7, 2025

Dear Thomas Kroenke:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Rachana Visaria -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233953

Device Name
Makani Science™ Respiration Monitoring System

Indications for Use *(Describe)*
The Makani Science™ Respiration Monitoring System is indicated for continuous, non-invasive, and real-time monitoring of a patient's breathing. It graphically displays respiration versus time and reports the respiratory rate value.

The Makani Science™ Respiration Monitoring System is intended to be used by healthcare professionals in healthcare facilities and dental offices on adult patients aged 22 or older. It is not intended to be used as an apnea monitor.

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.

K233953 510(k) Summary

(in accordance with 21 CFR 807.92)

Submission Date:	28 March 2025
Submitter:	Makani Science Inc. 5270 California Avenue, Suite 300 Irvine, CA 92617 USA
Submitter Correspondent	Dr. Michael Chu Phone: +1 (949) 427-5208 Email: michael@makaniscience.com
Application Correspondent:	Thomas Kroenke Principal Consultant Speed To Market, Inc. PO Box 3018 Nederland, CO 80466 USA tkroenke@speedtomarket.net +1 (303) 956 4232
Manufacturing Site (Contract):	Wistron Medical Technology Corporation 5F, No.5, XIN-AN Road Hsinchu Science Park Hsinchu City, Taiwan 300091
Trade Name:	Makani Science™ Respiration Monitoring System
Common and Classification Name:	Breathing Frequency Monitor
Classification Regulation:	21 CFR §868.2375
Product Code:	BZQ

Predicate Device:	*Predicate 510(k) Number*	*Predicate Manufacturer / Model*
	K220111	PMD Solutions / RespiraSense

K233953 510(k) Summary

(in accordance with 21 CFR 807.92)

Device Description: The Makani Science™ Respiration Monitoring System (Makani Science RMS) is a respiration rate (RR) monitoring system that consists of a pair of identical, battery-powered, wireless, Makani Science Ahe™ Respiration Sensors (Ahe Sensors – piezo-resistive strain sensors) and the Makani Science Ahe™ App (Ahe App), which is deployed and runs on an Apple® iPad®. The two (2) small and lightweight Ahe Sensors are paired to the Ahe App using Bluetooth Low Energy (BLE) 5.0 technology.

The Makani Science RMS is intended to be used by trained healthcare providers (HCPs) in the management of their patients.

The Ahe Sensors are single-patient use sensors and can be used up to 24 hours of continuous use.

The sensors are applied to the patient's intact skin using an adhesive tape built into the sensors and are made to be retained on the skin in non-ambulatory use situations, such as supine on a procedure room table or semi-recumbent in a dental chair. One sensor is applied to the patient's thoracic region and the other sensor is applied to the abdomen region. Correct placement of these sensors is important to the effectiveness of the device, and specific guidance is provided to the user in the labeling on where to place the sensors.

The Ahe App is a software application, which guides the user through system setup and monitoring using display screens. During use, the iPad is forced into guided access, or "kiosk" mode, which prevents the user from using any other applications during the monitoring session.

Once setup is complete and monitoring initiated, the Ahe App displays a graphical rendition and numerical value of the patient's RR. Low and high RR alarm thresholds provide a visual and audible notification if the patient's RR violates the user-determined alarm thresholds. Monitoring continues until the user terminates the monitoring session, at which time the Ahe App can save a report of the monitoring session to an external memory card, if desired by the user. No patient health information (PHI) is retained by the Ahe App after completion of the monitoring session.

The Makani Science RMS does not interact with any third-party medical or non-medical devices other than a memory card that is used to store a report of the patient's monitoring session.

K233953 510(k) Summary

(in accordance with 21 CFR 807.92)

Indications for Use: The Makani Science™ Respiration Monitoring System is indicated for continuous, non-invasive, and real-time monitoring of a patient's breathing. It graphically displays respiration versus time and reports the respiratory rate value.

The Makani Science™ Respiration Monitoring System is intended to be used by healthcare professionals in healthcare facilities and dental offices on adult patients aged 22 or older. It is not intended to be used as an apnea monitor.

Technology Comparison: The Makani Science™ Respiration Monitoring System (Makani Science RMS) employs the same technological characteristics as the predicate devices.

Characteristic	*Makani Science™ RMS (proposed device)*	*PMD Solutions RespiraSense (K220111) (Primary Predicate)*	*Discussion of Differences*
Indications for Use	The Makani Science™ Respiration Monitoring System is indicated for continuous, non-invasive, and real-time monitoring of a patient's breathing. It graphically displays respiration versus time and reports the respiratory rate value. The Makani Science™ Respiration Monitoring System is intended to be used by healthcare professionals in healthcare facilities and dental offices on adult patients aged 22 or older. It is not intended to be used as an apnea monitor.	The RespiraSense is indicated for continuous, non-invasive, and real-time monitoring of respiratory rate. RespiraSense is indicated for patients 18 years and older in hospitals, hospital-type facilities and while patients are mobile (e.g., walking). RespiraSense is not intended to be an apnoea monitor.	Similar. Device being limited to no-motion conditions and differences in the intended patient age does not raise new questions of safety and effectiveness.
Use Environments	Healthcare facilities and dental offices	Hospital and hospital-type facilities	Similar. Both devices are for use in healthcare facilities.
Patient Population	Adult patients aged 22 or older	Patients 18 years and older	Similar. The Makani Science RMS has a smaller patient population (18 versus 22 years of age) and is a subset of the PMD RespiraSense primary predicate.

Operating Principles	Piezo-resistive strain sensor	Piezo-electric sensor	Similar. The Makani Science RMS and PMD RespiraSense both measure the movement of the torso. Both systems calculate respiratory rate based on the respiratory waveform measured.
Patient Interface	Dual sensors adhesively attached to patient's chest	A reusable "lobe," i.e. device that attaches into a disposable, single sensor adhesively attached to patient's chest	Same. Both sensors are adhesively attached to the patient's chest.
Connection to Monitor	Bluetooth Low Energy (BLE) 5.0	BLE 4.2	Same.
Shelf Life	12 months	24 months	Similar.
RR Range	4 – 60 BPM	6 – 60 BPM	Similar.
RR Accuracy	± 3 BPM	± 3 BPM	Same.

Summary of Performance Testing:

Shelf-Life

The Ahe Sensor has a shelf life of 6 months from the date of manufacture, and was tested in accordance with the following Standard and internal shelf-life requirements:

- *ASTM F1980-21, Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.*

Biocompatibility

The patient-contact materials in the Ahe Sensor were tested for biocompatibility compliance in accordance with the following Standard and guidance document:

- *ISO 10993-1: 2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.*
- *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process," 04 Sep 20.*

Test results indicated that the patient-contact materials in the Ahe Sensor complies with the applicable Standard and guidance document as a surface contact, limited duration device, on intact skin only, for up to 24 hours of continuous use.

K233953 510(k) Summary

(in accordance with 21 CFR 807.92)

Software

The Makani Science RMS software, which includes the Ahe Sensor firmware and Ahe App software, were designed and developed in accordance with internal requirements and the following guidance documents and Standards:

- *FDA guidance: The content of premarket submissions for software contained in medical devices, 11 May 05.*
- *FDA guidance: Off-the-shelf software use in medical devices, 27 Sep 19.*
- *FDA guidance: General principles of software validation; Final guidance for industry and FDA staff, 11 Jan 02.*
- *Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, 02 Oct 14.*
- *Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, 06 Sep 17.*
- *IEC 62304: 2006, Am1:2015, Medical device software – Software life-cycle processes.*

Test results indicate that the Makani Science RMS complies with its predetermined specifications, guidance documents and Standards.

Electrical Safety

The Makani Science Ahe Sensor was tested for patient safety in accordance with the following Standards:

- *IEC 60601-1: 2005, Am1: 2012, Am2: 2020, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

Test results indicated that the Makani Science Ahe Sensor complies with the applicable Standards.

Electromagnetic Compatibility

The Makani Science RMS was tested for EMC in accordance with the following Standard:

- *IEC 60601-1-2: 2014, Am1: 2020, Medical Electrical Equipment, Part 1: Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests.*
- *ANSI C63.27 – 2017, American National Standard for Evaluation of Wireless Coexistence.*

Test results indicated that the Makani Science RMS complies with the applicable Standard.

Performance Testing – Bench

The Makani Science RMS was tested for performance in accordance with internal requirements, applicable Standards, and guidance document.

- *IEC 60601-1-6: 2013, Medical electrical equipment: General requirements for basic safety and essential performance – collateral standard: Usability.*
- *IEC 60601-1-8: 2020, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.*
- *IEC 62366-1: 2015, Medical devices – Application of usability engineering to medical devices.*
- *ISTA Procedure 3a, Packaged-products for Parcel Delivery System Shipment 70 kg (150 lb) or Less.*
- *FDA guidance: Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices, 06 Sep 17.*
- *FDA guidance: Radio Frequency Wireless Technology in Medical Devices, 14 Aug 13.*

Test results indicated that the Makani Science RMS complies with internal requirements, applicable Standards, and the guidance document.

- Additionally, the Makani Science RMS was successfully tested to demonstrate that the RR accuracy was maintained over 24 hours of continuous use.

Performance Testing – Clinical

Clinical testing was performed on 29 human subjects from the intended use population to validate the respiration rate accuracy of the Makani Science RMS compared to the gold standard, manually counted end-tidal CO_2 using an FDA-cleared capnogram. The testing included RR validation in all four available postures (supine, right side, left side, and reclined). Additional sup-group analysis demonstrated that RR accuracy was maintained regardless of patient demographics (sex, BMI (healthy, overweight, and obese), Fitzpatrick skin type, and the presence of comorbidities). Device accuracy was also maintained in the presence of artifacts (coughing, etc.) and following positional change (e.g., supine → reclined position).

Conclusion

Verification and validation activities were conducted to establish the performance and safety characteristics of the device modifications made to the Makani Science RMS. The results of these activities demonstrate that the Makani Science RMS is safe and effective when used in accordance with its intended use and labeling.

Therefore, the Makani Science RMS is considered substantially equivalent to the predicate device.