November 25, 2024

Knox Medical Diagnostics
℅ Carol Vierling
Senior Principal
Rqm+
2790 Mosside Blvd, Suite 800
Monroeville, Pennsylvania 15146

Re: K232588
Trade/Device Name: Aluna 2
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter For Spirometry
Regulatory Class: Class II
Product Code: BZH
Dated: October 25, 2024
Received: October 25, 2024

Dear Carol Vierling:

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
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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)*
K232588

Device Name
Aluna 2

Indications for Use *(Describe)*
Aluna 2 is intended for monitoring FEV1 (Forced exhalation in the first second) and PEF (Peak Expired Flow Rate) for home use. The device is designed for pediatric to adult users. Aluna is not recommended for children under 5 years of age. Additionally, the device may be used by clinicians for in-office monitoring.

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

DATE PREPARED
November 25, 2024

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DEVICE INFORMATION
- Device trade name, or proprietary name: Aluna 2
- Device common name: Peak flow meter for spirometry
- Classification: II
- 21 CFR 868.1860: Meter, peak flow, spirometry
- Product Code(s): BZH
- Panel: Anesthesiology
- Basis for submission: Device modifications

PREDICATE DEVICE IDENTIFICATION
Aluna 2 is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K193311	Aluna manufactured by Knox Medical Diagnostics	✓

DEVICE DESCRIPTION
Aluna 2 consists of three main components:
- A small hand-held peak flow meter that captures differential pressure, converts it to digital data points, and transmits the data to a mobile device via Bluetooth.
- A mobile application that collects and transmits the differential pressure readings from the spirometry device and processes it to estimate the exhaled air flow rate and volume.
- An Application Programming Interface (API) to facilitate communication with a cloud server used for data storage.

INDICATIONS FOR USE

Aluna 2 is intended for monitoring FEV1 (Forced exhalation in the first second) and PEF (Peak Expired Flow Rate) for home use. The device is designed for pediatric to adult users. Aluna is not recommended for children under 5 years of age. Additionally, the device may be used by clinicians for in-office monitoring.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Modifications are proposed to Aluna, the first generation device cleared under K193311. Modifications include minor cosmetic changes to hardware, adding additional capabilities to the software and changes to non-patient contacting materials.

The subject device has the same design and dimensions and uses similar materials as the first generation Aluna. The subject device has the same intended use and similar technological characteristics to the device cleared in K193311. Any difference in technological characteristics have undergone testing to ensure the device is as safe and effective as the predicate.

Substantial equivalence comparison between the subject device and the device cleared in K193311 is summarized in the table below.

	Subject Device	***Predicate Device***	***Comparison***
	Aluna 2 (K232588)	Aluna (K193311)	-
Indications for Use	Aluna 2 is intended for monitoring FEV1 (Forced exhalation in the first second) and PEF (Peak Expired Flow Rate) for home use. The device is designed for pediatric to adult users. Aluna is not recommended for children under 5 years of age. Additionally, the device may be used by clinicians for in-office monitoring.	Aluna is intended for monitoring FEV1 (Forced exhalation in the first second) and PEF (Peak Expired Flow Rate) for home use. The device is designed for children 5 years of age or older, adolescent and adult subjects. Additionally, the device may be used by clinicians for in-office monitoring.	Similar; Replacing age range of intended users with more concise language with the same meaning
Product Code / Regulation Number	BZH / 21 CFR 868.1860	BZH / 21 CFR 868.1860	Identical
Regulation Description	Peak-flow meter for spirometry	Peak-flow meter for spirometry	Identical
Rx / OTC	Rx or OTC	Rx or OTC	Identical
Mode of operation	Aluna 2 is a Lilly type pneumotachometer that uses a differential pressure sensor to measure the pressure difference across the stainless-steel mesh. The resulting pressure drop is used to calculate FEV1 and PEF.	Aluna is a Lilly type pneumotachometer that uses a differential pressure sensor to measure the pressure difference across the stainless-steel mesh. The resulting pressure drop is used to calculate FEV1 and PEF.	Identical
Dimensions	90.3 mm x 43 mm x 115.5 mm	90.3 mm x 43 mm x 115.5 mm	Identical
Weight	95 g	95 g	Identical
FEV1 Max	8 L	8 L	Identical
FEV1 accuracy	±2.5% or 0.05 L whichever is greater	±3% or 0.05 L whichever is greater	Similar; Tightened accuracy limits as required by 2019 ATS Update v. 2005 ATS Guidelines
FEV1 linearity	<2.5%	Unspecified	Similar; Stating new parameter and limit required by 2019 ATS Update that was not required in 2005 ATS Guidelines

	Subject Device	***Predicate Device***	***Comparison***
	Aluna 2 (K232588)	Aluna (K193311)	-
FEV1 repeatability	±2.5% or 0.05 L whichever is greater	Unspecified	Similar; Stating new parameter and limit required by 2019 ATS Update that was not required in 2005 ATS Guidelines
FEV1 impedance	≤0.15 kPa/(l/s)	Unspecified	Similar; Stating new parameter and limit required by 2019 ATS Update that was not required in 2005 ATS Guidelines
PEF max	14 L/s	14 L/s	Identical
PEF accuracy	±10% or 0.17 L/s whichever is greater	±10% or 0.3 L/s whichever is greater	Similar; Tightened accuracy limits as required by 2019 ATS Guidelines v. 2005 ATS Guidelines
PEF linearity	≤5%	Unspecified	Similar; Stating new parameter and limit required by 2019 ATS Update that was not required in 2005 ATS Guidelines
PEF resistance to flow	≤0.36 kPa/l/s	Unspecified	Similar; Stating new parameter and limit required by 2019 ATS Update that was not required in 2005 ATS Guidelines
PEF frequency response	≤0.25 l/s), or 12 %, whichever is greater	Unspecified	Similar; Stating new parameter and limit required by 2019 ATS Update that was not required in 2005 ATS Guidelines
Materials	Polymers, stainless steel	Polymers, stainless steel	Identical
Transmission Method	Bluetooth 4.0 LE	Bluetooth 4.0 LE	Identical
Power Source	Rechargeable battery	Rechargeable battery	Identical
Smartphone compatibility	iPhone (iOS 15 or later) Android (8 or later)	iPhone (iOS 11 or later)	Similar; Updated to include Android application and to include newer versions of iOS
Sterilization	Non-sterile	Non-sterile	Identical

	Subject Device	***Predicate Device***	***Comparison***
	Aluna 2 (K232588)	Aluna (K193311)	-
App functions	• Primary user interface • Data acquisition and processing • Data display • Data transmission to server	• Primary user interface • Data acquisition and processing • Data display • Data transmission to server	Identical
Game function	Yes or No depending on user preference	Yes	Similar; Updated to allow the game function to be switched off depending on user preference.
Data Storage	Cloud server	Cloud server	Identical
Data sharing	Yes, via email	Yes, via email	Identical

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety based on current industry standards:

- Electrical Safety
  - IEC 60601-1 *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
  - IEC 60601-1-6 *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability*
  - IEC 60601-1-11 *General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

- Electromagnetic Compatibility
  - IEC 60601-1-2 *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*

- Battery
  - IEC 62133-2 *Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems*

- FEV1/PEF measurement accuracy, repeatability, linearity, and Frequency Response per the American Thoracic Society Technical Statement on "Standardization of Spirometry 2019 Update" to meet the requirements of:
    - ISO 26782:2009 *Anaesthetic and respiratory equipment – Spirometers intended for the measurement of time forced expired volumes in humans*
    - ISO 23747:2015 *Anaesthetic and respiratory equipment – Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans*

- Software Verification
    - IEC 62304 *Medical device software — Software life cycle processes*

- Biocompatibility
    - FDA Guidance: *Use of International Standard ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (issued September 8, 2023)*
      Note: The patient contacting materials are identical to the predicate device. Biocompatibility testing was leveraged from the predicate device to support substantial equivalence.

- Cybersecurity
    - FDA Guidance: *Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (issued September 27, 2023)*

The results of these tests indicate that Aluna 2 is substantially equivalent to the predicate device.

SUMMARY OF CLINICAL TESTING
Clinical testing was not required.

CONCLUSION
Based on the testing performed, including software testing, electrical safety and EMC testing, battery testing and non-clinical performance bench testing, it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate device. Aluna 2 has the same design and dimensions and uses similar materials as the first generation Aluna. The subject device has the same intended use and similar technological characteristics as the predicate device. Aluna 2 is assessed to be substantially equivalent to the predicate device.