March 25, 2020

Knox Medical Diagnostics, Inc.
% Pierre Bounaud
Senior Regulatory Specialist
Acknowledge Regulatory Strategies
2251 San Diego Ave, Suite B-257
San Diego, California 92110

Re: K193311
Trade/Device Name: Aluna
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter For Spirometry
Regulatory Class: Class II
Product Code: BZH
Dated: February 26, 2020
Received: February 27, 2020

Dear Pierre Bounaud:

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 Michael Ryan
Division Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193311

Device Name
Aluna

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

DATE PREPARED
March 25, 2020

MANUFACTURER AND 510(k) OWNER
Aluna
345 California Street, Suite 600, San Francisco, CA 94104, USA
Telephone: +1 (415) 320-0690
Official Contact: Charvi Shetty, CEO

REPRESENTATIVE/CONSULTANT
Pierre Bounaud, Ph.D.
Allison C. Komiyama, Ph.D., R.A.C.
AcKnowledge Regulatory Strategies, LLC
Telephone: +1 (619) 458-9547
Email: pbounaud@acknowledge-rs.com
akomiyama@acknowledge-rs.com
Website : www.AcKnowledge-RS.com

DEVICE CLASSIFICATION

Proprietary Name/Trade Name:	Aluna
Common Name:	Peak-flow meter
Regulation Number:	21 CFR 868.1860
Class:	II
Product Code:	BZH
Premarket Review:	OHT1/ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices (DHT1C)
Review Panel:	Anesthesiology

PREDICATE DEVICE IDENTIFICATION
Aluna is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K181666	Smart One / MIR Medical International Research	✓
K152276	Wing Smart FEV1 and Peak Flow Meter / Sparo Inc.	

DEVICE DESCRIPTION
Aluna is a small hand-held peak flow meter that captures lung health information and makes it available through a mobile application. Aluna is intended for monitoring FEV1 (Forced Expiratory Volume in one second) and PEF (Peak Expiratory Flow) for over-the-counter use. Aluna is designed for use by 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.

INDICATIONS FOR USE

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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Aluna is substantially equivalent to the predicate device based on the information summarized here:

The subject device has a similar design, dimensions and uses similar materials as the devices cleared in K181666 and in K152276. The subject device has the same intended use and similar technological characteristics to the devices cleared in K181666 and in K152276.

Technological differences of the subject device compared to the predicate device cleared in K181666 include:

- rechargeable lithium ion battery
- data storage on a cloud server
- game function

These technological differences have undergone testing to ensure the device is as safe and effective as the predicate.

The game function in the subject device is similar to the game function in the predicate device cleared in K152276. The role of the game function is to encourage users to take readings and to perform correct spirometry measurements with the use of game rewards as incentives.

Substantial equivalence comparison between subject device and devices cleared in K181666 and in K152276 is summarized in the table below.

	Subject Device	***Predicate Device***	***Predicate Device***
	Aluna	Smart One (K181666)	Wing Smart FEV1 and Peak Flow Meter (K152276)
Indications for Use	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 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.	Smart One is intended for home use by patients to monitor PEF (Peak Expiratory Flow) and FEV1 (Forced Expiratory Volume in one second). The device is designed for children greater than five years of age, adolescent and adult subjects.	Wing 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. Wing is not recommended for children under 5 years of age.
Product Code / Regulation Number	BZH / 21 CFR 868.1860	BZH / 21 CFR 868.1860	BZH / 21 CFR 868.1860
Regulation Description	Peak-flow meter for spirometry	Peak-flow meter for spirometry	Peak-flow meter for spirometry
Rx/OTC	OTC	OTC	OTC
Mode of operation	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.	The device is equipped with a plastic mouthpiece connected to a turbine flow meter based on the infrared interruption principle. The device detects the signals generated by the turbine and measures the exhalation flow. At the end of the expiration, the device calculates the PEF and FEV1.	The Wing uses an acoustic transducer to measure frequency of oscillation caused by the airstream to calculate FEV1 and PEF
Dimensions	90.3 mm x 43 mm x 115.5 mm	49 mm x 109 mm x 21 mm	3.2 x 2.4 x 1.5 inches (81 x 61 x 37mm)
Weight	95 g	60.7 g	70g
FEV1 Max	8 L	10 L	9.99 L

	Subject Device	***Predicate Device***	***Predicate Device***
	Aluna	Smart One (K181666)	Wing Smart FEV1 and Peak Flow Meter (K152276)
FEV1 accuracy	±3% or 0.05 L whichever is greater	±3% or 0.1 L whichever is greater	±5% or 0.1 L whichever is greater
PEF max	14 L/s	16 L/s	15 L/s
PEF accuracy	±10% or 0.3 L/s whichever is greater	±10% or 0.4 L/s whichever is greater	±12% or 0.417 L/s whichever is greater
Materials	Polymers, stainless steel	Plastic body	Plastic body
Transmission Method	Bluetooth 4.0 LE	Bluetooth 4.0 LE	Audio cable
Power Source	Rechargeable battery	2x1.5V AAA batteries	Smartphone battery
Smartphone compatibility	iPhone (iOS 11 or later)	iPhone, Android devices	iPhone and iPad (iOS 9 or later)
Sterilization	Non-sterile	Non-sterile	Non-sterile
App functions	• Primary user interface • Data acquisition and processing • Data display • Data transmission to server	• Primary user interface • Data acquisition and processing • Data display and storage	• Primary user interface • Data acquisition and processing • Data display • Data transmission to server
Game function	Yes	No	Yes
Data Storage	Cloud server	Phone	Cloud server
Data sharing	Yes, via email	Yes, via email	Yes, via email

SUMMARY OF NON-CLINICAL TESTING

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

- Biocompatibility testing per ISO 10993-1, ANSI/AAMI/ISO 10993-5, ISO 10993-10, ISO 18562-1, ISO 18562-2, and ISO 18562-3
- Software testing per IEC 62304
- Electrical safety testing per IEC 60601-1, IEC 60601-1-6, and IEC 60601-1-11
- EMC testing per IEC 60601-1-2
- Battery testing per IEC 62133-2
- Wireless coexistence testing per ANSI PC63.27
- Non-clinical performance bench testing including:
    - FEV1/PEF measurement accuracy and repeatability per 2005 American Thoracic Society document ATS/ERS Task Force: Standardization of Lung Function Testing
    - Ambient temperature and ambient pressure testing

- Usability testing per IEC 62366-1

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

CONCLUSION

Based on the testing performed, including biocompatibility, software testing, electrical safety and EMC testing, battery testing, wireless coexistence 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. The similar indications for use, technological characteristics, and performance characteristics for the proposed Aluna are assessed to be substantially equivalent to the predicate device.