November 3, 2022

Sound Land Corp.
Chi-Hsun Hung
QC Manager
No.32, Keji 1st Rd., Guishan Dist.
Taoyuan, 33383
Taiwan

Re: K220466
Trade/Device Name: ibiomedi Electronic Stethoscope ES-2020
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD,
Dated: October 6, 2022
Received: October 6, 2022

Dear Chi-Hsun Hung:

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,

LCDR Stephen Browning
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)*

K220466

Device Name

ibiomedi Electronic Stethoscope ES-2020

Indications for Use *(Describe)*

The ibiomedi Electronic Stethoscope ES-2020 is used to detect sound from the heart, arteries, veins, breathing sounds from the anterior/posterior/lateral chest and throat sounds in the neck. The chest piece is designed for children who are over two years old, teenagers and adults. It can be applied to any body type and can only be used for the purpose of medical diagnosis in clinics or hospitals.

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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This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. §807.92.

1. **Preparation Date:** 09/24/2021

2. **Applicant/Sponsor:** Sound Land Corp.
No.32, Keji 1st Rd., Guishan Dist., Taoyuan City 33383, Taiwan

3. **Contact Person:** Hung, Chi-Hsun
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4. **Proprietary Name:** ibiomedi Electronic Stethoscope ES-2020

5. **Common Name:** Electronic Stethoscope

6. **Classification Name:** 21 CFR 870.1875
Stethoscope, Electronic

7. **Classification Identification:** Class II

8. **Product Codes:** DQD

9. **Predicate Device:** Stethoscope, Electronic K160023

10. **Device Description:**

The ibiomedi Electronic Stethoscope ES-2020 detects sounds from the heart, arteries, veins, breathing sounds from the anterior/posterior/lateral chest and throat sounds in the neck of patients. The sounds are transmitted to the user's ears through accessories such as earphones.

User interface includes
A: Power button, frequency response mode button, volume button
B: Power indicator, wireless transmission indicator, frequency response mode indicator, volume indicator.

Turn on the ibiomedi Electronic Stethoscope ES-2020 and connect to the wireless device via Bluetooth to transmit and store sounds. When the ibiomedi Electronic Stethoscope ES-2020 and the connected wireless device have walls, human bodies and other barriers, the effective range of Bluetooth transmission will be affected. It is recommended to reduce the distance between the ibiomedi Electronic Stethoscope ES-2020 and the connected wireless device to improve Bluetooth connection.Power to the device is provided by two AAA 1.5V batteries.

The associated accessories include.

- Small chest piece: For children with diaphragm.
- Large chest piece: For adult with diaphragm.
- Audio line: For connecting external speakers.
- 1MORE Earphones: For medical personnel to connect the ibiomedi Electronic Stethoscope ES-2020.

11. Indications for Use:

The ibiomedi Electronic Stethoscope ES-2020 is used to detect sound from the heart, arteries, veins, breathing sounds from the anterior/posterior/lateral chest and throat sounds in the neck. The chest piece is designed for children who are over two years old, teenagers and adults. It can be applied to any body type and can only be used for the purpose of medical diagnosis in clinics or hospitals.

12. Comparison of Technological Characteristics with The Predicate Device:

The ibiomedi Electronic Stethoscope ES-2020 uses a miniature microphone to pick up sound through the chest piece and uses noise-cancelling technology to filter murmurs to distinguish heart sounds with a frequency of 20~200Hz, lung sounds with a frequency of 100~1000Hz, and all sounds within 1200Hz. And it can amplify the sound up to 50X, which is helpful for medical personnel to make judgments.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Chest piece & miniature microphone: To use a miniature microphone to pick up sound through the chest piece.
- Noise-cancelling technology: To filter murmurs and distinguish the frequency.
- Sound amplification: To amplify sound of specific frequency.

The following technological differences exist between the subject and predicate devices:

- Use earphones instead of ear tubes.
- Replaceable chest piece.
- Use only AAA alkaline batteries.

13. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Tests included on O-rings and 3M 1525L Polyethylene from the chest piece that contact with the patient's skin.

The biocompatibility evaluation for the ibiomedi Electronic Stethoscope ES-2020 was conducted in accordance with modified ISO 10993-10:2010, Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization. The Guinea Pig Maximization Test (GPMT) was used to evaluate the hypersensitivity-inducing effect of the test article, and ISO 10993-10: 2010, Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization. The potential of the test article under test to produce irritation was valuated following dermal application of the test article extracts from polar and non-polar extractions, and ISO 10993-5: 2009, Biological evaluation of medical devices-Part 5: Tests for in vitro cytotoxicity.

- Skin sensitization study guinea pig maximization test
- Skin irritation test in rabbits
- Cytotoxicity study for biocompatibility

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the ibiomedi Electronic Stethoscope ES-2020. The system complies with the IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 and EN 60601-1: 2006 + A1: 2013 and AAMI/IEC 60601-1:2005 + AMD 1:2012 and CAN/CSA-C22.2 No. 60601-1:14 standards for safety, and IEC 60601-1-2: 2014 / EN 60601-1-2: 2015 standard for EMC.

Software Verification and Validation Testing

Sound Land considers the level of concern to be " Minor ". According to the guidance " Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices " Document issued on: May 11, 2005, The definition of the " Minor " is as follows: " the level of concern in Minor if failures or latent design flaws are unlikely to cause any injury to the patient or operator ".

The software of the ibiomedi Electronic Stethoscope ES-2020 has passed the test and met the requirements of the above standards, the ibiomedi Electronic Stethoscope ES-2020 is quite safe and reliable in terms of software.

Performance Testing

Tests were conducted to determine whether the amplification of sound was affected by the use of earphones. According to the results, the performance data presented by traditional stethoscope and the subject device are similar.

Usability Study
Usability testing of the ibiomedi Electronic Stethoscope ES-2020 included usability study of 15 doctors and 15 nurses.

Usability evaluation objective with the acceptance criteria:
At least 85% of participants with no experience in this type of product will be able to use it properly after reading Instruction Manual for around 30 minutes.

Summary:
The summative evaluation objective of usability is met. For the purposes of ISO 14971, the residual risks associated with sability shall be presumed to be acceptable.

14. Conclusions
The results of the bench performance tests, usability studies, the hardware and software verification and validation demonstrate that the ibiomedi Electronic Stethoscope ES-2020 should perform as intended in the specified use conditions. The data demonstrate that the ibiomedi Electronic Stethoscope ES-2020 device is substantially equivalent to the predicate device that is currently marketed for the same intended use.