August 2, 2023

Smartsound Corporation
Jungho Lee
Representative
171, Yangjaecheon-ro, Gangnam-gu
Seoul, 06302
Korea, South

Re: K230613
Trade/Device Name: SKEEPER
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: March 4, 2023
Received: March 6, 2023

Dear Jungho Lee:

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,

Stephen C. Browning -S

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)*
K230613

Device Name
SKEEPER

Indications for Use *(Describe)*
SKEEPER is an electronic stethoscope that collects, filters, and amplifies the sound of a person's heart, lungs, and abdomen. It is intended for use by professional users in clinical environments or by lay users in non-clinical environments. It is not intended for self-diagnosis.

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

K230613

1. Submitter Information

Manufacturer: SMARTSOUND CORPORATION

171, Yangjaecheon-ro, Gangnam-gu, Seoul, Republic of Korea

Contact Person: Jungho Lee / Representative

Tel: +82-2-575-2252

Fax: +82-2-575-2201

e-mail: jhojholee@ismartsound.com

Date Prepared: March 04, 2023

2. Device Information

Trade Name: SKEEPER

Model Number: SM-300 and SKEEPER APP

Common Name: Electronic Stethoscope

Product Code: DQD

Regulation Number: 21 CFR 870.1875

Class: 2

3. Predicate Device Information

Predicate Device: K200776 (Eko CORE)

Reference Device: K083903 (3M LITTMANN ELECTRONIC STETHOSCOPE, MODEL 3200)

4. Description of the Device

SKEEPER is an electronic stethoscope used to collect and measure the sounds inside the body, and it consists of an electronic stethoscope (SM-300) and a mobile application (SKEEPER PRO APP).

When the diaphragm at the bottom of the SM-300 is lightly attached to the body part to be measured, such as the heart, lungs, or abdomen, the diaphragm vibrates due to the sound inside the human body and generates a sound. This sound is collected using a microphone and converted into an electrical signal. After that, the electrical signal is filtered and amplified for each frequency band set according to the mode of the measurement site, amplified, and output to earphones or transmitted to the SKEEPER APP installed on the mobile platform, and then the sound is output through the earphone or speaker of the corresponding platform.

The SKEEPER PRO APP graphs the waveform of the sound received by the SM-300. It also stores and plays back sound data and analyzes heart rate.

5. Indication for Use

SKEEPER is an electronic stethoscope that collects, filters, and amplifies the sound of a person's heart, lungs, and abdomen. It is intended for use by professional users in clinical environments or by lay users in non-clinical environments. It is not intended for self-diagnosis.

6. Technological Characteristics

	Subject Device	Predicate Device	Reference Device
510(k) Number	K230613	K200776	K083903
Proprietary Name	SKEEPER, Model SM-300 and SKEEPER APP	Eko CORE	3M LITTMANN ELECTRONIC STETHOSCOPE, MODEL 3200
Manufacturer	SMARTSOUND CORPORATION	Eko Devices, Inc.	3M Health Care
Regulatory Class	Class II	Class II	Class II
Regulation Number	21 CFR 870.1875	21 CFR 870.1875	21 CFR 870.1875
Product Code	DQD	DQD	DQD
Indication for Use	SKEEPER is an electronic stethoscope that collects, filters, and amplifies the sound of a person's heart, lungs, and abdomen. It is intended for use by professional users in clinical environments or by lay users in non-clinical environments. It is not intended for self-diagnosis.	The Eko CORE is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. Eko CORE is intended for use on pediatric and adult patients. The Eko CORE is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis	The 3MTM Littmann Electronic Stethoscope, Model 3200 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment.
Signal Input Method	Microphone (MEMS)	Microphone (MEMS)	Piezoelectric Sensor
Frequency response range	• Heart mode: 30-600Hz (emphasizes 50 Hz ~ 300 Hz) • Lung mode: 50-2000Hz (emphasizes 100 Hz ~ 1200 Hz) • Abdomen Mode: 30-800Hz	20Hz to 2KHz	• Bell: 20-1000 Hz (emphasizes 20-200 Hz) • Diaphragm 20-2000 Hz (emphasizes 100-500 Hz) • Extended Rang 20-2000 Hz

	(emphasizes 60 Hz ~ 400 Hz)		(emphasizes 50-500 Hz)
Sound Amplification	Yes	Yes	Yes
Volume Control	Yes	Yes	Yes
Record and Playback Sounds	Yes	Yes	Yes
Save & Share Recordings	Yes	Yes	Yes
Power Source	Rechargeable Lithium-ion Battery	Rechargeable Lithium-ion Battery	Single AA, NiMH (rechargeable) or Lithium batteries may be used
Data transfer to Compatible Computing platform	Mobile and tablets (SKEEPER-APP)	Yes (Eko App)	Yes (StethAssist™)
Wireless Technology	Bluetooth®	Bluetooth®	Bluetooth®
Software Function	○ Receive and store the sound data ○ Display the phonocardiograph of heart sound data ○ Reply the sound data ○ Measure the heart rate (BPM)	○ Receive and store the sound data ○ Display the phonocardiograph of heart sound data ○ Reply the sound data	○ Receive and store the sound data ○ Display the phonocardiograph of heart sound data ○ Reply the sound data ○ Measure the heart rate (BPM)

- **Indication for Use**

Subject, predicate, and reference devices are the same in that they collect, filter, and amplify sound inside the human body.
The subject and predicate devices are intended to be used by medical personnel and lay users in clinical and non-clinical environment.
Therefore, the indication for use of subject device is substantially the same as predicate device.

- **Signal Input Method**

The subjective device's signal input method is the same as that of the predicate device, which is different from the reference device.

- **Frequency response range**

The subjective device changes the frequency of the sound collected depending on the mode selection. A predicate device collects a wide range of sound frequencies in one mode. The reference device also has different collected frequencies depending on the mode.
The frequency band used throughout is 30 Hz to 2000 Hz for the target device and 20 Hz to 2000 Hz for the subject and reference devices. The frequencies used by the subject and reference devices are substantially equivalent because they cover the frequency bands used by the subject device.

- **Functions**

Sound Amplification, Volume Control, Record and Playback Sounds, Save & Share Recordings, Power Source, and wireless communication method are all the same for all devices.

- **Application software**

Using software to store, play, and graphically display sounds is all the same.
Predicate devices do not have the function of analyzing sound, but Reference devices do have the function of analyzing heart rate. This is the same as the function of analyzing heart rate for the Subject device.

7. Summary of Non-Clinical Data

The following non-clinical data were provided in support of the substantial equivalence determination.

Electrical safety and electromagnetic compatibility(IEC 60601-1, IEC 60601-1-11, and IEC 60601-1-2), Biocompatibility(ISO 10993-1, ISO 10993-5, ISO 10993-10, ISO 10993-23), Software verification and validation (IEC 62304), Wireless coexistence (ANSI IEEE C63.27) and Bench testing

10. Summary of Clinical Data

Clinical Data was not required to demonstrate the substantial equivalence.

11. Conclusion

SKEEPER has the same intended uses and similar indications as the predicate device in that it filters and amplifies the sound of the human body. The two devices are also identical in that they send sound data to mobile applications for storage, playback, and visualization.

The difference between SKEEPER and predicate device is that SKEEPER's mobile application provides heart rate analysis, but predicate device's mobile application does not provide heart rate analysis. However, heart rate analysis is provided in the reference device's mobile application.

These functional differences do not introduce new intended uses and do not raise other concerns about safety and effectiveness when used as labeled.

Therefore, SKEEPER is substantially equivalent to a predicate device.