September 14, 2020

Sonavi Labs, Inc.
Ian Mclane
Chief Technology Officer
1100 Wicomico St., Suite 600
Baltimore, Maryland 21230

Re: K200862
Trade/Device Name: Feelix Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: August 11, 2020
Received: August 12, 2020

Dear Ian Mclane:

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 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200862

Device Name
Feelix Stethoscope

Indications for Use *(Describe)*
The Feelix Stethoscope is intended for the detection, amplification and recording of sounds from the heart, lungs, anterior and posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with selective frequency ranges. It can be used on any person undergoing a physical examination.

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 - K200862

(per 21 CFR 807.92)

Submitter Information

Name	Sonavi Labs, Inc.
Address	1100 Wicomico St., Suite 600 Baltimore, MD 21230
Phone Number	(410) 417-8167
Contact Person	Ian McLane Chief Technology Officer
Date Prepared	March 30, 2020

Device Information

Trade Name	Feelix Stethoscope
Common Name	Electronic Stethoscope
Classification	Stethoscope 21 CFR 870.1875 (Product Code DQD)

Predicate Device Information

Device Name	M3DICINE's Stethee Pro 1
K Number	K172296

Device Description

Sonavi Labs, in collaboration with Johns Hopkins University, has developed a next generation stethoscope with pristine digital audio to help clinicians and healthcare workers detect, amplify, and record sounds during physical examination. The Feelix Stethoscope (Feelix) re-engineers the classic stethoscope and offers three major improvements: (1) more uniform sensitivity over its entire face so that sound quality is less dependent on placement on the body (2) leading noise suppression and sound volume control, and (3) onboard real-time algorithms so the device can operate as a stand-alone rather than requiring connection to a computer.

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Intended Use

To detect, amplify, and record sounds during a physical examination

Indications for Use

The Feelix Stethoscope is intended for the detection, amplification and recording of sounds from the heart, lungs, anterior and posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with selective frequency ranges. It can be used on any person undergoing a physical examination.

Comparison to Predicate

The Feelix Stethoscope's indications for use statement includes a couple minor differences from the predicate device. These changes were implemented to better represent expected use, without impacting the underlying intended use.

Technological Characteristics

As shown in Table 1, many technological similarities exist between the subject and predicate devices. The operating mechanism utilized in the Feelix Stethoscope is microphone-based, which is the same as the predicate device. Both devices demonstrate both safety and effectiveness by the ability to obtain a sound (signal acquisition) and to suppress surrounding noise without impacting the sound of interest. This is proven through scientific evidence presented in the premarket notification. Other technological characteristics of the Feelix Stethoscope, including software, EMC and ES testing, are similar to the predicate device.

Table 1 - Technological Comparison

Characteristic	**Subject Device** **Feelix Electronic Stethoscope**	**Predicate Device (K172296)** **M3DICINE Stethee™ Pro 1**	**Comparison**
Trade Name	Feelix (or Feelix Pro) Stethoscope	Stethee™ Pro 1	Different Trade name differences have no impact on substantial equivalence.
Common Name	Electronic Stethoscope	Electronic Stethoscope	Same
510(K) Number	Unknown	K172296	Different 510(k) numbers have no impact on substantial equivalence.
Regulation Classification	21 CFR 870.1875(b)	21 CFR 870.1875(b)	Same
Product Code	DQD	DQD	Same
Intended Use	Detection, amplification and recording of sounds	Detection, amplification and recording of sounds	Same Note that the recording of sounds is present in M3DICINE's marketing materials (e.g., website).

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Characteristic	Subject Device Feelix Electronic Stethoscope	Predicate Device (K172296) M3DICINE Stethee™ Pro 1	Comparison
Indications for Use	The Feelix Stethoscope is intended for the detection, amplification and recording of sounds from the heart, lungs, anterior and posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with selective frequency ranges. It can be used on any person undergoing a physical examination.	The Stethee™ Pro 1 is an electronic stethoscope 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. It can be used on any person undergoing a physical assessment.	Equivalent Minor differences in language add clarity and do not change the overall intended use of the device.
Anatomical Use Areas	Heart, lungs, anterior and posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs	Heart, lungs, arteries, veins, and other internal organs	Equivalent Minor differences in language add clarity and do not change the overall intended use of the device.
Use Environment	Clinical, Transport (e.g., Ambulance), and Home	unknown	Undetermined Predicate device marketing materials state that device is "telehealth ready" which implies the same use environment as Feelix. Clinical and transport environments are commonplace for stethoscope use.
Rx or OTC	Rx	Rx	Same
Power Source	Lithium	Lithium	Same
Battery Life	< 3 hours (continuous use)	unknown	Undetermined Differences in battery life do not have an impact on safety or effectiveness.
Wire/Wireless Charging	Both	Wired	Different The additional capability for Feelix to be charged wirelessly does not have an impact on safety or effectiveness.
Direct Listening	Sounds can be heard in real time using a Bluetooth enabled headset; sounds can also be heard in real time by wired headset	Sounds can be heard in real time using a Bluetooth enabled headset	Equivalent The additional capability for Feelix to have direct listening by headset does not have an impact on safety or effectiveness. This function is common to other electronic stethoscopes.

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Characteristic	Subject Device Feelix Electronic Stethoscope	Predicate Device (K172296) M3DICINE Stethee™ Pro 1	Comparison
Noise Reduction Type	Proprietary Noise Cancellation (Active)	Proprietary Noise Cancellation	Equivalent Effectiveness is proven out in testing for both devices.
Amplification	Up to 25X	Up to 24X	Equivalent Both devices have a ceiling to prevent excessively loud outputs that could cause hearing damage.
Number of Recordings (Capacity)	50 recordings	None on device itself	Different The additional capability for Feelix is a non-medical feature that does not impact safety or effectiveness.
Length of Recordings	10 seconds	20 seconds	Different Differences in recording length do not have an impact on safety or effectiveness.
Software	Proprietary Software Compliant to IEC 62304:2015	Proprietary Software Compliant to IEC 62304:2015	Same
Data Transfer	Bluetooth or Wired	Bluetooth	Equivalent The additional capability for Feelix to have a wired connection does not have an impact on safety or effectiveness. This connection type is common to other electronic stethoscopes.
Cleaning	Isopropyl alcohol	Isopropyl alcohol	Same
ES & EMC	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-1-12	IEC 60601-1 IEC 60601-1-2 [unknown if additional collateral tests were conducted]	Different Additional tests performed by Sonavi Labs do not raise new or different questions of safety or effectiveness.

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Characteristic	Subject Device Feelix Electronic Stethoscope	Predicate Device (K172296) M3DICINE Stethee™ Pro 1	Comparison
Performance Testing	Usability Testing Acoustic Performance	Performance (over range of operation)	Different The additional usability test performed by Sonavi Labs does not raise new or different questions of safety or effectiveness. It is likely that the performance testing was different, as no information is available on the predicate device's testing regimen. The subject device's acoustic performance test demonstrated that the device was as effective as other legally marketed electronic stethoscopes.

Performance Data

Bench performance data were collected to support a substantial equivalence determination. Animal and clinical testing were not necessary. Bench performance testing included software verification and validation, electrical safety and EMC testing (including home and EMT collaterals), usability testing, and evaluation of signal acquisition and noise suppression functions. Performance test results demonstrate reasonable assurance that the Feelix Stethoscope can safely and effectively detect, amplify, and record sounds during a physical examination. These data suggest the Feelix Stethoscope is as safe and as effective as the identified predicate device.

Conclusions

The Feelix Stethoscope and its predicate device have the same intended use and similar indications, both serving as medical devices to detect, amplify, and record sounds during a physical examination. As described above, the minor technological differences between the Feelix Stethoscope and its predicate do not present any new or different issues of safety or effectiveness. Performance testing further confirms that these differences do not raise different questions of safety or effectiveness. Based upon this analysis and valid scientific evidence it can be concluded that the Feelix Stethoscope is substantially equivalent to its predicate device.