November 9, 2017

M3dicine Pty. Ltd.
℅ Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K172296
Trade/Device Name: Stethee™ Pro 1
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: July 27, 2017
Received: July 31, 2017

Dear Mark Job:

This letter corrects our substantially equivalent letter of October 30, 2017.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172296

Device Name

Stethee™ Pro 1

Indications for Use *(Describe)*

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.

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.

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"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

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

510(k) Submitter M3DICINE Pty Ltd.
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8 Clunies Ross Court,
Eight Mile Plains QLD 4113
AUSTRALIA

Contact person Ginger Cantor, RAC
Centaur Consulting, LLC
Phone: (715) 307-1850
centaurconsultingllc@gmail.com

Date Summary Prepared: October 12, 2017

Trade Name: Stethee™ Pro 1
Classification Name: Electronic Stethoscope
Regulation Number: 21 CFR §870.1875(b)
Product Code: DQD
Classification Panel: Cardiovascular
Device Classification: Class II

Intended Use/Indications for Use

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.

Predicate Device:

3M™ Littmann® Model 3200 (K083903)

Description of Device:

The M3DICINE Stethee™ Pro 1 is an electronic stethoscope that picks up sounds of the heart, arteries, veins, lungs and other internal organs. Stethee™ Pro 1 provides capability for auscultation in frequencies from 20-2000Hz.

After amplification and filtering, the sounds are transferred to the user's ears via any Bluetooth connected headphones. The Stethee™ Pro 1 includes features that permit it to record and store sounds on a peripheral smart device (e.g., mobile phone) by transferring the sounds as an audio buffer to the smart device via a Bluetooth® connection. The smart device makes use of a downloaded companion stand-alone Mobile Medical Application (MMA), Stethee™ App, to record, manage and replay the captured patient sounds on the smart device.

Stethee™ App is also able to display the audio file as a phonocardiograph (21 CFR 870.2390) on the user's smart device and can use the audio file to calculate and display a simple Heart Rate. Stethee™ App does not direct or influence the performance of Stethee™ Pro 1.

The Stethee™ Pro 1 device user interface includes a simple push down mechanism ("control knob") to start recording. It has a light-emitting diode (LED) display ring which indicates the device's status state (ON or OFF, charge status, and Bluetooth® synchronization status).

The Stethee™ Pro 1 operates on a rechargeable certified 3.7V lithium ion polymer battery.

The Stethee™ Pro 1 incorporates embedded software. The embedded software controls all the various features found in the Stethee™ Pro 1, such as sound capture, digital signal processing, volume control, LED display ring, and Bluetooth® transfer.

Comparison to Predicate:

Classification Comparison			
	Stethee™ Pro 1	**Predicate** **3M™ Littmann® Model 3200** **510(k) 083903**	**Comment**
Classification	Electronic Stethoscope	Electronic Stethoscope	Same
Regulation	21 CFR 870.1875(b) Class II device	21 CFR 870.1875(b) Class II device	Same
FDA Proceed	DQD	DQD	Same

Intended Use/Indications for Use/Contraindications Comparison			
	Stethee™ Pro 1	**3M™ Littmann® Model 3200 FDA 510(k) K083903**	**Comment**
Intended Use/Indications for Use	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.	The 3M™ 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.	Substantially equivalent
Contraindications	None	None	Same

Technical Characteristics Comparison			
Feature	**Stethee™ Pro 1**	**3M™ Littmann® Model 3200 (K083903)**	**Comments**
Pickup sensor and processing	Microphone (-22 dB sensitivity) Sampling Rate: 16kHz Bit Rate: 16 bits	Piezoelectric sensor Sampling Rate: 4 kHz Bit Rate: 16 bits	Both mechanisms convert sound waves into a digital signal via digital signal processing. They are functionally equivalent.
Frequency Response	Responsive from 20-2000Hz	Bell (20-1000 Hz) Diaphragm (20-2000 Hz) "Extended Range" (20-2000 Hz)	Note that 3M Littmann® has qualified these response claims in their Instruction for Use as follows: Littmann®'s Bell mode emphasizes 20-200Hz). Littmann®'s Diaphragm mode emphasizes 100-500Hz). Littmann®'s "Extended Range" provides more low frequency response between 50-500Hz.
Maximum Sound Level	Amplifies up to 24X	Amplifies up to 24X	Same
Volume Control	Yes, in 8 steps	Yes, in 8 steps	Same

Technical Characteristics Comparison			
Feature	**Stethee™ Pro 1**	**3M™ Littmann® Model 3200 (K083903)**	**Comments**
Power Source	Rechargeable Lithium-ion polymer battery	Single AA, NiMH (rechargeable) or Lithium batteries may be used	The Littmann® Model 3200 uses a single AA alkaline battery as the default setting but states rechargeable NiMH or Lithium batteries may be used.
Low Battery Indicator	Yes	Yes	The color of Stethee™ Pro 1's LEDs on the device indicate low battery condition; Littmann® Model 3200 uses a low battery icon in the LCD display on the stethoscope.
Operating Controls and Indicators	ON/OFF features by electronics. LEDs on device indicate devices status (ON/OFF, charging, Bluetooth® synchronization).	ON/OFF features by electronics. LCD display on device indicates device status.	Stethee™ Pro 1 uses a tapping mechanism to turn it on and off. Littmann® Model 3200 uses a physical on/off button. Both are controlled through electronics and software.
Heart Rate: Detection and Display	Yes -using companion Stethee™ App (a MMA).	Yes – displayed on the Littmann® Model 3200 integrated LCD.	Substantially equivalent. Heart Rate is not displayed on device, but is displayed on a peripheral device running the companion Stethee™ App.
Heart Rate: Minimum Audio Sample Requirements	Requires initial 0.3-2 second recording.	Requires initial 5 second recording.	Substantially equivalent
Heart Rate: Methodology	Performs continuous real-time calculation after initial 0.3-2 second sampling and updates heart rate display after each heart beat	The heart rate is updated every 2 seconds after the initial 5 second sampling.	Substantially equivalent
Heart Rate: Range of Detection and Accuracy	30 -200 BPM with an allowable readout error rate of no greater than ±10 % (i.e., 10% consistency) of the input rate or ±5 bpm.	30 -199 BPM with an allowable readout error rate of no greater than ±10 % (i.e., 10% consistency) of the input rate.	Substantially equivalent
Heart Rate-Handling of inconsistent sounds	Inconsistent sounds displayed on Stethee™ App GUI as "—".	Inconsistent sounds displayed on Littmann® Model 3200 LCD screen as "—".	Substantially equivalent

Technical Characteristics Comparison			
Feature	**Stethee™ Pro 1**	**3M™ Littmann® Model 3200 (K083903)**	**Comments**
Direct Listening	Stethee™ Pro 1 sounds can be listened to in real time using a Bluetooth® enabled headset.	Littmann® Model 3200 allows direct listening to sounds in real time through the device's attached binaurals.	Substantially equivalent. The healthcare professional can use the device to listen in real-time.
Recording and Playback	Not on the device itself, but with Stethee™ App.	Yes – stores twelve (12) 30 second tracks on device	Stethee™ App can be used to record and playback the sounds on the User's Smart device. Number of sounds is only limited by the phone's memory.
Visualization	Sounds can be visualized as phonocardiograph using companion software Stethee™ App	Sounds can be visualized as phonocardiograph using software StethAssist™.	Substantially equivalent. Both devices rely on external software to visualize the sound, under the same software classification of phonocardiograph (21 CFR 870.2390).
Wireless Technology and Peripheral Platform Compatibility	Yes – uses Bluetooth® at 2.4 GHz Compatible with Android and iOS devices	Yes – uses Bluetooth® at 2.4 GHz, Compatible with Android devices, not compatible with iOS devices*	*Littmann® web page states it is not compatible with Apple devices. Littmann® Model 3200 manual states an additional USB Bluetooth® adaptor is required for this function.
Ambient & Frictional Noise Reduction Technology	Yes	Yes	Substantially equivalent.

Performance Testing
M3DICINE submitted performance testing information in this 510(k) demonstrating that the Stethee™ Pro 1 can perform over its intended range of operation (20-2000Hz). Comparative performance testing submitted in the 510(k) demonstrated the two devices perform in a substantially equivalent manner.

Safety, Electromagnetic Compatibility (EMC) and Coexistence Compliance
M3DICINE submitted information demonstrating compliance with the requirements of IEC 60601-1, *Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance* (2012 Reprint; Ed. 3.1) and with the US translation of the IEC 60601-1 international standard (AAMI ES60601-1:2005 +A1).

M3DICINE also submitted information demonstrating full compliance with the international standard IEC 60601-1-2:2007, *Medical Electrical Equipment –Part 1: General Requirements for Safety: Collateral Standard: Electromagnetic Compatibility Requirements and Tests (Ed. 3.0).*

In addition to general safety and EMC testing, M3DICINE has successfully addressed FDA's requirements for wireless coexistence testing of the Stethee™ Pro 1.

Software Testing and Standards Compliance
M3DICINE submitted software verification and validation information and documentation required under FDA's Guidance *Content of Premarket Submission for Software Contained in Medical Devices (May 11, 2005).* M3DICINE is compliant with the requirements of *IEC 62304:2015, Medical Device Software - Software Life Cycle Processes.*

Animal and Clinical Testing
No animal or clinical testing was submitted in this 510(k).

Biocompatibility
M3DICINE's biocompatibility assessment and testing used standard risk assessment techniques of ISO14971:2007 and consideration of FDA & internationally recognized guidelines and standards (including ISO 10993-1 series). M3DICINE has concluded that the Stethee™ Pro 1 is safe for its intended use.

Conclusion

M3DICINE's evaluation of the substantial equivalence of the Stethee™ Pro 1 (with companion Stethee™ App) to the 3M™ Littmann® Model 3200 was based on a comparison of device classification, intended use, indications for use and contraindications, and technical characteristics. M3DICINE also compared the two device's risks and labeling. Based on this comparison, M3DICINE concludes that Stethee™ Pro 1 is substantially equivalent to the 3M™ Littmann® Model 3200 predicate device (K083903) without raising any new safety or effectiveness issues.