October 9, 2020

M3DICINE Pty Ltd.
% Ginger Cantor
Founder/Principal Consultant
Centaur Consulting LLC
W9281 710th Avenue
River Falls, Wisconsin 54022

Re: K193631
Trade/Device Name: Stethee Pro 1
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, DRG, DQC, BZQ
Dated: December 24, 2019
Received: December 27, 2019

Dear Ginger Cantor:

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,

LT 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)*
K193631

Device Name
Stethee Pro 1

Indications for Use *(Describe)*
The Stethee™ Pro 1 is an electronic stethoscope intended for screening and 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 or without the use of selective frequencies. It can be used on any person undergoing a physical assessment.

Stethee Pro 1 is intended for use with the Stethee Pro Software System, whose features enable recording, playback, visualization, analysis, management and reporting of patient samples, and sharing this data with other authorized users.

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.

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M3DICINE

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.
Level 1, 88 Brandl Street
Eight Mile Plains QLD 4113
AUSTRALIA

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

Date Summary Prepared: August 19, 2020

Trade Name: Stethee™ Pro 1 System
(Stethee™ Pro 1 with Stethee Pro Software System)
Classification Name: Electronic Stethoscope
Regulation Number: 21 CFR §870.1875(b)
Primary Product Code: DQD
Secondary Product Codes: DQC, DRG, BZQ
Classification Panel: Cardiovascular
Device Classification: Class II

Intended Use/Indications for Use

The M3DICINE Stethee™ Pro 1 is an electronic stethoscope intended for medical screening or diagnostic purposes only. Stethee Pro 1 may be used for detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with or without the use of selective filters. It can be used on any person undergoing a physical assessment.

Stethee Pro 1 is intended for use with the Stethee Pro Software System, whose features enable sample recording, playback, visualization, analysis, reporting and sharing with other authorized users.

Predicate Device:

Stethee Pro 1 (and Stethee App) [K172296]

Reference Devices:

Littmann® Model 3200 Electronic Stethoscope [K083903]

Capnostream™ 35, Portable Respiratory Monitor [K150272]

Description of Device:

Stethee Pro 1:

The Stethee Pro 1 is an electronic stethoscope intended for medical screening or diagnostic purposes only. Stethee Pro 1 may be used for detection and amplification of sounds from the heart, lungs, arteries, veins, and other internal organs with or without the use of selective filters. It can be used on any person undergoing a physical assessment.

The Stethee Pro 1 consists of hardware and embedded software which controls all of the various features found in the device, such as sound capture, digital signal processing, volume control, haptic feedback for user, LED display ring, and wireless data transfer (via Bluetooth®). No patient data is stored on the Stethee Pro 1 device itself.

After amplification and filtering of the sounds detected, Stethee Pro 1 transfers the sounds to the User's ears via any Bluetooth® connected headphones, or by wired headphones connected to Stethee Pro 1 using an AUX adaptor at the device's USB port.

The Stethee Pro 1 also includes features that permit it to stream sounds to a peripheral smart device (e.g., mobile phone) as an audio buffer to a smart device (iOS or Android) via a Bluetooth® connection. The audio buffer is handled on the smart device by a separate stand-alone software application called the Stethee Pro Software System.

Stethee Pro Software System:

Stethee Pro Software System (SPS) is a series of software applications (Stethee Pro Mobile Applications and the Stethee Pro Central Web Application) that work with the Stethee Pro 1 electronic stethoscope. Stethee Pro Software System is supported by M3DICINE's proprietary software platform M3DICINE Cloud Services (MCS) which provides various services including database, security, and core business logic services so that services for data sharing and multiple sign-ins from multiple devices can be implemented.

Comparison to Predicate and Reference Devices:

Comparison of Classification, Regulation and Pro Codes				
	Modified Device System **Stethee™ Pro 1 and Stethee Pro Software System** **510(k) [K193631]**	**Predicate Device System** **Stethee™ Pro 1 and Stethee App** **510(k) [K172296]**	**Reference Device** **Littmann® Model 3200 Electronic Stethoscope** **510(k) [K083903]**	**Reference Device** **Capnostream™ 35 Portable Respiratory Monitor** **510(k) [K150272]**
Classification	Stethee Pro 1 Electronic Stethoscope: Class II Stethee Pro Software System: Class II	Stethee Pro 1 Electronic Stethoscope: Class II Stethee App Software: Class I, 510(k) exempt	Electronic Stethoscope, Class II	Carbon Dioxide Gas Analyzer, Class II
Regulation	Stethee Pro 1 21 CFR 870.1875(b) Stethee Pro Software System: 21 CFR 870.2910, 21 CFR 870.2390 21 CFR 868.2375	Stethee Pro 1: 21 CFR 870.1875(b) Stethee App: 21 CFR 870.2390	21 CFR 870.1875(b)	21 CFR 868.1400
FDA Pro Code	Primary Product Code: DQD Secondary Product Codes: DRG, DQC, BZQ	Stethee Pro 1: DQD, Stethee App: DQC	Product Code: DQD	Primary Product Code: CCK Secondary Product Codes: DQA, MNR

Comparison of Intended Use/Indications for Use				
Device	**Stethee Pro 1 and Stethee Pro Software System 510k TBD**	**Stethee Pro 1 and Stethee App [K172296]**	**Reference Device 3M™ Littmann® Model 3200 510(k) [K083903]**	**Reference Device Capnostream™ 35 510(k) [K150272]**
Intended Use / Indications for Use	The Stethee™ Pro 1 is an electronic stethoscope intended for screening and 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 or without the use of selective frequencies. It can be used on any person undergoing a physical assessment. Stethee Pro 1 is intended for use with the Stethee Pro Software System, whose features enable recording, playback, visualization, analysis, management and reporting of patient samples, and sharing this data with other authorized users.	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.	The Capnostream™ 35 is a portable capnograph/pulse oximeter, intended to provide professionally trained health care providers with continuous non-invasive monitoring of carbon dioxide concentration of the expired and inspired breath, respiration rate, arterial oxygen saturation (SpO2) and pulse rate of adult, pediatric, and neonatal patients. The pulse oximeter is intended for use during both no motion and motion conditions and for patients who are well or poorly perfused. The Capnostream™35 also provides the clinician with integrated pulmonary index (IPI), apnea per hour (A/hr) and oxygen desaturation index (ODI) values. IPI is intended for pediatric and adult patients only. A/hr and ODI are intended for age 22 and up. The device is intended for use in hospitals, hospital-type facilities, during intra-hospital transport, and out-of-hospital Emergency Medical Service applications that include ground and air transport.
Contraindications	None	None	None	None

Comparison of Technical Principles of Operation and Features					
Feature	**Stethee Pro 1 and Stethee Pro Software System** **510k [K193631]**	**Stethee Pro 1 and Stethee App** **[K172296]**	**Comments Regarding SE comparison of** **SP1/SPS System [K193631]** **To** **SP1/Stethee App [K172296]**	**Reference Device Littmann® Model 3200** **510(k) [K083903]**	**Reference Device Capnostream™ 35** **510(k) [K150272]**
Pickup Sensor and Processing	Microphone (-26 dBFS sensitivity) Sampling Rate: 16 kHz Bit Rate: 16 bits	Microphone (-22 dB sensitivity) Sampling Rate: 16 kHz Bit Rate: 16 bits	Substantially Equivalent	Piezoelectric sensor Sampling Rate: 4 kHz Bit Rate: 16 bits	Not Applicable
Frequency Response	Responsive from 20-2000 Hz (Extended Mode (Default)) Bell (20-1000 Hz) Diaphragm (100-500 Hz) Mid-Range (50-500 Hz) Heart (20-150Hz)	Responsive from 20-2000 Hz	SP1 Extended Mode [K193631] is same as default filter described in [K172296] Bell: a filter amplifies 20-1000 Hz with emphasis at 20-200 Hz Diaphragm: a filter amplifies from 20-2000 Hz with emphasis at 100-500 Hz Mid-Range filter amplifies 20-2000 Hz with emphasis of low frequency sounds of 50-500Hz Heart: a filter that amplifies 20-500 Hz with emphasis from 20-150 Hz	Bell (20-1000 Hz) Diaphragm (20-2000 Hz) “Extended Range” (20-2000 Hz)	Not Applicable
Maximum Sound Level	Amplifies up to 24X on the Stethee Pro 1 device	Amplifies up to 24X on the Stethee Pro 1 device	Same	Amplifies up to 24X	Not Applicable
Volume Control	Yes, in 8 steps	Yes, in 8 steps	Same	Yes, in 8 steps	Not Applicable
Power Source	Rechargeable Lithium-ion polymer battery	Rechargeable Lithium-ion polymer battery	Same	Single AA, NiMH (rechargeable) or Lithium batteries may be used	Not Applicable
Low Battery Indicator	Yes	Yes	Same	Yes	Not Applicable
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. LEDs on device indicate devices status (ON/OFF, charging, Bluetooth® synchronization).	Same	ON/OFF features by electronics. LCD display on device indicates device status.	Not Applicable

Comparison of Technical Principles of Operation and Features (Continued)					
Feature	**Stethee Pro 1 (SP1) and Stethee Pro Software System (SPS)** **510(k) K193631**	**Stethee Pro 1 and Stethee App** **510(k) [K172296]**	**Comments Regarding SE comparison of SP1/SPS System [K193631] to SP1/Stethee App [K172296]**	**Reference Device Littmann® Model 3200** **510(k) [K083903]**	**Reference Device Capnostream™ 35 Portable Respiratory Monitor** **510(k) [K150272]**
Direct Listening	Stethee Pro 1 sounds can be listened to in real time using a Bluetooth® enabled headset or a wired headset.	Stethee Pro 1 sounds can be listened to in real time using a Bluetooth® enabled headset.	New Feature – device can accommodate direct listening by use of a wired headset connected through USB port	Littmann® Model 3200 allows direct listening to sounds in real time through the device's attached binaurals.	Not Applicable
Recording and Playback	Not on the Stethee Pro 1 device itself, but with use of companion Stethee Pro Software System	Not on the Stethee Pro 1 device itself, but with use of companion Stethee App	Substantially Equivalent	Yes – stores twelve (12) 30 second tracks on device	Not Applicable
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 and iOS devices	Same	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.	Not Applicable* Device has wireless features but comparison as reference device not performed.
Ambient and Frictional Noise Reduction	Yes	Yes	Same	Yes	Not Applicable
Heart Rate: Detection and Display	Yes -using companion Stethee Pro Software System	Yes -using companion Stethee™ App (a MMA).	Same	Yes – displayed on the Littmann® Model 3200 integrated LCD.	Not Applicable
Heart Rate: Minimum Audio Sample Requirements	Requires minimum initial 5 second recording.	Requires minimum initial 5 second recording.	Same	Requires initial 5 second recording.	Not Applicable

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Comparison of Technical Principles of Operation and Features (Continued)					
Feature	**Stethee Pro 1 (SP1) and Stethee Pro Software System (SPS)** **510(k) K193631**	**Stethee Pro 1 and Stethee App** **510(k) [K172296]**	**Comments Regarding SE comparison of SP1/SPS System [K193631] to SP1/Stethee App [K172296]**	**Reference Device Littmann® Model 3200** **510(k) [K083903]**	**Reference Device Capnostream™ 35 Portable Respiratory Monitor** **510(k) [K150272]**
Heart Rate: Methodology	Performs continuous real-time calculation after initial sampling and updates heart rate display after each heartbeat	Performs continuous real-time calculation after initial sampling and updates heart rate display after each heartbeat	Same	The heart rate is updated every 2 seconds after the initial 5 second sampling.	Not Applicable
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, whichever is less.	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, whichever is less	Same	30 -199 BPM with an allowable readout error rate of no greater than ±10 % (i.e., 10% consistency) of the input rate.	Not Applicable
Visualization Modes	Sounds can be visualized as phonocardiograph (PCG) and/or Spectrogram using companion software Stethee Pro Software System	Sounds can be visualized as phonocardiograph (PCG) using companion software Stethee™ App	New Feature of Spectrogram Visualization	Sounds can be visualized as phonocardiograph using software StethAssist™.	Not Applicable
Heart Cycle Duration Display	Individual and average systole and diastole duration (milliseconds) calculated from PCG displayed linearly and as Aida Cycle (a circular representation of PCG)	Not Applicable	New Feature' this new feature was clinically validated against the reference PCG from cleared Littmann Model 3200 device [K083903]	Note: Littmann Model 3200 System serves as Reference PCG, but it does not calculate and display to user the systole and diastole durations from its PCG.	Not Applicable
Heart Rate- Handling of Inconsistent Sounds	Inconsistent sounds displayed on Stethee Pro Mobile Applications and Stethee Pro Central Web App GUI as "--".	Inconsistent sounds displayed on Stethee App GUI as "--".	Same analysis, handling and display feature, now extended to new Stethee Pro Central Web as interface (part of SPS)	Inconsistent sounds displayed on Littmann® Model 3200 LCD screen as "--".	Not Applicable
Respiration Rate	Companion apps in the Stethee Pro Software accurately calculate and display respiration rates in respirations per minute for a clinically validated range of 6 - 50 breaths per minute ±1 breath per min.	Not Applicable	New Feature – The Respiration Rate feature was clinically validated against the Reference Device Capnostream 35.	Not Applicable	Capnostream™ 35 monitors and displays patient's respiration rate over a range of 0-150 breaths per minute (bpm) with the following claimed accuracy: 0-70 bpm: ±1 bpm 71-120 bpm: ±2 bpm 121-150 bpm: ±3 bpm

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Comparison of Technical Principles of Operation and Features (Continued)					
Feature	**Stethee Pro 1 (SP1) and Stethee Pro Software System (SPS)** **510(k) K193631**	**Stethee Pro 1 and Stethee App** **510(k) [K172296]**	**Comments Regarding SE comparison of SP1/SPS System [K193631] to SP1/Stethee App [K172296]**	**Reference Device Littmann® Model 3200** **510(k) [K083903]**	**Reference Device Capnostream™ 35 Portable Respiratory Monitor** **510(k) [K150272]**
Geolocation	SPS Applications allow user to collect/identify the geolocation where and environmental conditions when patient sample was collected.	Not Applicable	New Feature	Not Applicable	Not Applicable
Sample Comparison	Patient Sample analysis (heart rate, systole duration, diastole duration) can be compared with those of the previous sample or the averaged of those parameters for all the samples collected from the patient. This allows the user to see how patient condition has changed over time.	Not Applicable	New Feature of Sample Comparison Analysis	Not Applicable	Not Applicable
Data Sharing	Healthcare professional can share patient files with another authorized HCP through Stethee Pro Cloud Services.	Not Applicable	New Feature of Data Sharing	Not Applicable	Not Applicable
Report Generation	Users can generate patient reports using Stethee Pro Software System features	Not Applicable	New Feature of Report Generation	Not Applicable	Not Applicable
Web Portal to Access Recorded Data	Stethee Pro Central Web Application provides patient management features, sample management features, dashboard, visualization and display of heart analytics and respiration rate.	Not Applicable	New platform for accessing data stored on Stethee Pro Cloud Services	Not Applicable	Not Applicable

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Comparison of Technical Principles of Operation and Features (Continued)					
Feature	**Stethee Pro 1 (SP1) and Stethee Pro Software System (SPS)** **510(k) K193631**	**Stethee Pro 1 and Stethee App** **510(k) [K172296]**	**Comments Regarding SE comparison of SP1/SPS System [K193631] to SP1/Stethee App [K172296]**	**Reference Device Littmann® Model 3200** **510(k) [K083903]**	**Reference Device Capnostream™ 35 Portable Respiratory Monitor** **510(k) [K150272]**
Control of Stethee Pro 1 Features	Stethee Pro Mobile Applications provides user the ability to monitor, and configure Stethee Pro 1 settings: including: battery level, firmware version, filters, heartbeat locator	Not Applicable	New Feature – Stethee Pro Quick Settings	Not Applicable	Not Applicable
Android Application	Stethee Android Application's patient management features, sample management features, analysis heart sound visualization and displaying of heart analytics and respiration rate.	Not Applicable	New platform for accessing data for the Stethee Pro Cloud Services; system now supports Android as well as iOS devices.	Compatible with Android devices.	Not Applicable

Performance Testing
M3DICINE submitted performance testing information in this 510(k) demonstrating that the Stethee Pro 1 and the companion stand-alone Stethee Pro Software System both perform as intended.

Performance testing included bench testing and software verification and software simulated validation testing. Additionally, successful clinical validation of the performance accuracy of the device's machine learning analysis algorithms was performed against the listed reference devices, as identified in the summary comparison tables above, with documentation submitted in this 510(k).

Safety, Electromagnetic Compatibility (EMC) and Coexistence Compliance
M3DICINE submitted information demonstrating the Stethee Pro 1 complied 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) as translated into the US national version (AAMI ES60601-1:2005 +A1).

M3DICINE also submitted information demonstrating the Stethee Pro 1 fully complies with the international standard IEC 60601-1-2:2014, *Medical Electrical Equipment –Part 1: General Requirements for Safety: Collateral Standard: Electromagnetic Compatibility Requirements and Tests (Ed. 4.0)*.

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 for the Stethee Pro 1 and the Stethee Pro Software System 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 Testing
No animal testing was submitted in this 510(k).

Conclusion

M3DICINE's evaluation of substantial equivalence was based on comparison of the Stethee Pro 1 (with companion stand-alone Stethee Pro Software System) to the predicate Stethee Pro 1 and companion stand-alone software Stethee Pro App cleared under [K172296]. Successful clinical validation was performed against the identified References Devices. The comparison was related to device classification, intended use/indications for use, contraindications, and technical features and operating characteristics.

Based on this comparison, M3DICINE concludes that Stethee Pro 1 and Stethee Pro Software System is substantially equivalent to the predicate Stethee Pro 1 and companion stand-alone software Stethee Pro App cleared under [K172296].