January 25, 2018

StethoCloud Pty. Ltd (CliniCloud)
% Dave Yungvirt
Senior RA/QA Consultant
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K173448
Trade/Device Name: CliniCloud Stethoscope
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: November 2, 2017
Received: November 6, 2017

Dear Dave Yungvirt:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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)*
K173448

Device Name

CliniCloud Stethoscope

Indications for Use *(Describe)*

The CliniCloud Stethoscope is a digital stethoscope intended for periodic recording of lung and heart sounds to a smartphone device, via the CliniCloud app. It is intended to be used for persons of all ages. The device is for medical diagnostic purposes only.

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

K173448

1. Submission Sponsor

StethoCloud Pty. Ltd (CliniCloud)

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Australia

Contact: Andrew Lin

Title: CEO

2. Submission Correspondent

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Contact: Diane Sudduth

Title: Senior Consultant, RA

3. Date Prepared

1/15/2018

4. Device IDentification

Trade/Proprietary Name: CliniCloud Stethoscope

Common/Usual Name: Electronic Stethoscope

Classification Name: Electronic Stethoscope

Regulation Number: 870.1875

Product Code: DQD

Device Class: Class II

Classification Panel: Cardiovascular

5. Legally Marketed Predicate Device:

K050159, 3M™ Littmann® Electronic Stethoscope, 3M Health Care. Primary Predicate.
We have identified "K083903, 3M™ Littmann® Electronic Stethoscope, 3M Health Care" as a Reference Device. The reference device is used to support the heart rate estimation technology available in the subject device and the data transfer ability of its digital signals to an auxiliary device (which was needed to directly assess the frequency response of the subject device).

6. Indications for Use Statement

The CliniCloud Stethoscope is a digital stethoscope intended for periodic recording of lung and heart sounds to a smartphone device, via the CliniCloud app. It is intended to be used for persons of all ages. The device is for medical diagnostic purposes only.

7. Device Description

The CliniCloud stethoscope is a battery powered electronic stethoscope intended for the periodic recording of lung and heart sounds to a smartphone via a CliniCloud micro-USB to 4-pole audio cable. The CliniCloud Stethoscope features no user interface or speaker and must be used in conjunction with the CliniCloud app on a compatible smartphone. It is intended to be used for persons of all ages.

8. Substantial Equivalence Discussion

The following table compares the CliniCloud Stethoscope to the predicate device with respect to indications for use, principles of operation, technological characteristics, materials, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

TabLe 5A – Comparison of Characteristics for Primary Predicate

Manufacturer	**StethoCLouD Pty LtD (CLiniCLouD)**	**3M HeaLth Care**
Trade Name	**CliniClouD Stethoscope (SPL-999)**	**3M Littmann Electronic Stethoscope Model 3000**
510(k) Number	K173448	K050159
ProDuct CoDe	DQD	DQD

Manufacturer	**StethoCLouD Pty LtD (CLiniCLouD)**	**3M HeaLth Care**
TraDe Name	**CLiniCLouD Stethoscope SPL-999**	**3M Littmann ELectronic Stethoscope MoDeL 3000**
ReguLation Number	870.1875	870.1875
ReguLation Name	Electronic Stethoscope	Electronic Stethoscope
InDications for Use	The CliniCloud Stethoscope is a digital stethoscope intended for periodic recording of lung and heart sounds to a smartphone device, via the CliniCloud app. It is intended to be used for persons of all ages. The device is for medical diagnostic purposes only.	The 3M™ Littmann® Electronic Stethoscope Model 3000 is intended for medical diagnostic purposes only. It may be used for the amplification of heart, lung, arteries, veins, and other internal organs with the use of selective frequency. It can be used on any person undergoing a physical assessment.
Prescription use	No	No
Measurement frequency range	20 – 22050 Hz	20 - 500 Hz
DispLay Heart Rate	Yes	No
Permits Data transfer of storeD DigitaL signaLs	Yes	No
PoWer source	1 x CR2032 coin battery (maximum 3.0 V)	1 x AA battery (maximum 1.5 V)
SignaL transmission	Wired connection to a compatible smartphone	No signal transmission capabilities
Diaphragm Diameter	34 mm	29 mm
Chestpiece technoLogy	Single sided	Single sided
User interface	Smartphone device display	No display, 4-button keypad
LoW battery inDication	Yes	Yes
AmpLification	N/A	Up to 18 Times amplification
Waterproof	No	No

Manufacturer	StethoCLouD Pty LtD (CLiniCLouD)	3M HeaLth Care
TraDe Name	CLiniCLouD Stethoscope SPL-999	3M Littmann ELectronic Stethoscope MoDeL 3000
Patient contacting materiaL	Plastic	Plastic

Note on the "InDications for Use": Both stethoscopes are indicated for medical diagnostic purposes only. The CliniCloud Stethoscope is not indicated for use to amplify sounds from arteries, veins and other internal organs. This does not affect the safety or effectiveness of the CliniCloud Stethoscope within its intended use of recording heart and lung sounds.

9. Non-CLinicaL Data

Non-clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- AAMI ANSI ES 60601-1:2005/(R)2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2014 Medical Electrical Equipment, Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
- IEC 60601-1-11:2010 Radiators Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment [Including: Technical Corrigendum 1 (2011)]
- IEC 62366:2007 Medical devices - Application of usability engineering to medical devices.
- "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued on May 11, 2005"
- ISO 10993-1:2009 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process; all requirements were met.
- ISO 10993-5:2009 Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity; all requirements were met.
- ISO 10993-10:2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization; all requirements were met.
- FDA Guidance – "Design Considerations for Devices Intended for Home Use (November, 24, 2014)"

Other performance testing conducted include:

- Frequency response equivalence testing from 20 to 2000Hz against a reference 510k cleared stethoscope
- Accuracy testing of heart rate estimation benchmarked with a 510k cleared pulse oximeter
- Validation of device cleaning instructions considering likely use
- Validation that frequencies across entire functional range can be reproduced on the smartphone and when transmitted remotely

10. CLinicaL Performance Data

There was no human clinical testing required to support the medical device as the indications for use is equivalent to the predicate device. These types of devices, including the predicate devices, have been on the market for many years with proven safety and efficacy for the use of the device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of SubstantiaL EquivaLence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Or the device has the same intended use and different technological characteristics, but can be demonstrated that the device is substantially equivalent to the predicate device, and that the new device does not raise additional questions regarding its safety and effectiveness as compared to the predicate device.

The CliniCloud Stethoscope, as designed and manufactured, is determined to be substantially equivalent to the referenced predicate device(s).