DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 15, 2016

Stratoscientific, Inc.
% Jim West
Principal Consultant
Biomedical Devices Of Kansas
1205 E Us 24-40 Highway
Tonganoxie, Kansas 66086

Re: K160016
Trade/Device Name: Steth IO
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: May 27, 2016
Received: June 7, 2016

Dear Jim West:

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 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 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 yours,

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)*
K160016

Device Name
Steth IO

Indications for Use *(Describe)*
The StratoScientific Steth IO Stethoscope and Phonocardiogram Model 1.0 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, and lungs with the use of selective frequency ranges. It has been tested for use on adults 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.

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."

Traditional 510(k) Summary

Update for Addendum 2

1. Summary Date: 27 May 2016

2. Applicant Name:
StratoScientific, Inc.
1574 Northwest 190th Street
Shoreline, WA 98177 USA
Ph: (425)876-4310
Establishment Registration Number: Pending FDA Registration is pending.

1. Submission Correspondent: On behalf of StratoScientific Inc., the following consultant is assigned the responsibility of submission correspondence:
Jim West, Principal Consultant
Biomedical Devices of Kansas, LLC
1205 E US 24-40 Highway
Tonganoxie, KS 66086
Ph: 913.845.3851 ext. 106

2. Trade Name: Steth IO®

3. Common Name: Smartphone Stethoscope and Phonocardiogram

4. Description: Steth IO is an acoustic device that is used in conjunction with a smartphone to collect heart and lung sounds. Steth IO attaches to the back of the smartphone and contains an acoustic wave guide that channels sound from the Steth IO chest piece to the smartphone's microphone, while also acting as a protective covering for the phone. The Steth IO smartphone application software performs real-time analysis so the user can hear the sounds using headphones, and visualize the sound using the on-screen phonocardiogram. The device is capable of recording sound and phonocardiogram data, allowing healthcare providers to capture biological sounds and send the data to other healthcare providers or for review at a later time. Steth IO is intended for use as a diagnostic aid, enabling the healthcare provider to identify sounds and any abnormalities that may be present.

5. Manufacturing Site:
6. (Hardware)
Biomedical Devices of Kansas
1205 E. US 24-40 Highway
Tonganoxie, KS 66086 USA
Ph: (913)845-3851
Establishment Registration Number: 3007124677

7. Classification Regulation, Class & Product Code & Panel:
21 CFR 870.1875(b)
Class II
Product Code: DQD
Panel: Cardiovascular

8. Compliance to Special Controls / Performance Standards: Compliance to the following recognized consensus standards is declared:

Quality, Risk Management & Process related Standards.
CFR 21CFR820: Part 820 - QUALITY SYSTEM REGULATION,
IEC 62304:2006 Medical device software - Software life cycle processes,
ISO 13485:2012 Medical devices - Quality management systems - Requirements for regulatory purposes,
ISO 14971:2012 Medical devices - Application of risk management to medical devices,

Technical/ Product Specific Standards
ASTM D 4169:2009 Standard Practice for Performance Testing of Shipping Containers and Systems,
IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential

performance, 3rd

Labeling Standards
EN 1041:2008 The system labelling shall comply with BS EN 1041:2008 Information supplied by the manufacturer of medical devices,
ISO 15223-1:2012 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirement,

Biocompatibility standards
ISO 10993:2010 The parts of the system that come into contact with humans shall comply with AAMI / ANSI / ISO 10993:2010 (Biological evaluation of medical devices),

9. Intended Use of Device

PRODUCT REQUIREMENTS DOCUMENT – Novilase Model LTS-2	
Indication for use: Intended use:	The StratoScientific Steth IO Stethoscope and Phonocardiogram Model 1.0 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, and lungs with the use of selective frequency ranges. It has been tested for use on adults undergoing a physical assessment. The StratoScientific Steth IO Stethoscope and Phonocardiogram Model 1.0 is intended for medical diagnostic purposes only. It may be used for the detection and amplification of sounds from the heart, and lungs with the use of selective frequency ranges. It has been tested for use on adults undergoing a physical assessment.
Intended User	Health Care Providers
Intended Use Environment:	Medical Facilities Hospitals Outpatient Clinics Physician Offices
Targeted Patient Population:	Adults undergoing a physical assessment.
Contraindications:	Open skin lesions at site of examination

10. Predicate Device(s):
    510(k) Number: K083903
    Manufacturer: 3M Company
    Trade Name: 3M Littmann Electronic Stethoscope, Model 3200
    Product Code: DQD
    Classification: 870.1875

11. Comparison to Predicates
    The proposed device and the predicate device have the same/equivalent intended use, intended user, intended use environment and targeted patient population. The predicate device chosen to establish substantial equivalence is the 3M Littmann Electronic Stethoscope, Model 3200, cleared under 510(k) K083903; used in conjunction with the Zargis StethAssist phonocardiogram software. It should be noted that phonocardiograms are 510(k) exempt devices per 870.2390. This predicate was selected based on a reference product, the ViScope Electronic Stethoscope (K100531) which used the same principal predicate in their 510(k) for an electronic stethoscope.

    The main differences between Steth IO, Model 1.0 Smartphone Stethoscope and Phonocardiogram and the Predicate 3M Littmann Electronic Stethoscope, Model 3200 are included in the Executive Summary VOL_002/001 Table 2-1.1, copied here for reader convenience:

Table 2-1.1 Differences between Steth IO and Predicate Efficacy/Safety Concerns

Feature / Function	Steth IO (Subject Device)	3M Model 3200 with Zargis StethAssist (Predicate Device)	Comments on Efficacy/Safety
Diaphragm Material	Fiberglass / Epoxy sheet	Polyurethane coated silicone	The reference device uses the fiberglass/epoxy interface for the diaphragm. This is equivalent for exempt device (Cardiology III).
Energy Source	Lithium Ion Battery provided by smartphone	Alkaline battery, Lithium Ion battery, or NIMH battery. Lithium Ion used for below freezing temperatures	Specific energy power source in this case does not have a significant impact on efficacy or performance of the stethoscope device.
Signal Input Method	Analog collection of sound waves to smartphone microphone	Sound waves collected via a transducer	Both mechanisms convert sound waves into a digital signal. They are functionally equivalent.
Audio Output Method	Audio port and headphones	Earbuds	Both devices transmit sound energy into the ear through devices inserted into the ear. While the mechanism is different the result is functionally equivalent.
Signal Storage	Dependant on capacity of smartphone. Each recording is last 1 minute of evaluation	Limited to 12 – 30 second recordings	By using a smartphone operating platform, the Steth IO has a much greater capacity for data storage, thus improving efficacy. Does not affect safety or efficacy.
Signal Transmission for Visualization	No transmission necessary for analysis and review, processed and displayed on smartphone	Bluetooth transmission to compatible PC	Improved efficacy as there is no need for data transmission for processing, so decreased opportunity for error. No safety or efficacy concerns.
Form Factor	Device that is held in the doctors hand is the form of the smartphone	Similar to traditional stethoscope	Because the stethoscope is built into the case attached to the smartphone the handling of the device by the health care provider is slightly different. Usability validation has shown that clinicians experience no difficulty in understanding how to use and operate the device and because the patient contact diaphragm is very similar to traditional stethoscopes there appear to be no challenges in understanding how the device is used.
Dedicated Device vs. iPhone	Operates on iPhone 6 smartphone using built in hardware and operating system	Dedicated proprietary hardware	The smartphone hardware and operating system is fully capable of exceeding the requirements for an electronic stethoscope. The operating platform of the iPhone does not introduce any safety or efficacy concerns.

12. Conclusions

StratoScientific believes the proposed Steth IO (Model 1.0) and its predicates the 3M Littmann Electronic Stethoscope, Model 3200 used in conjunction with the Zargis StethAssist phonocardiogram software, are substantially equivalent in their intended use, intended users, intended use environment and indications for use. They share similar design and technology characteristics as well as the same fundamental scientific operational technology. The differences that exist between the devices do not affect the relative safety and/or effectiveness.