March 24, 2022

StratoScientific
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K220196
Trade/Device Name: Steth IO Spot
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: March 21, 2022
Received: March 22, 2022

Dear Prithul Bom:

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,

LCDR 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220196

Device Name
Steth IO Spot

Indications for Use *(Describe)*
The Steth IO Spot is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data, whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. Steth IO Spot is intended for use on individuals undergoing physical examination. The Steth IO Spot is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis or emergency use.

OTC use: Steth IO Spot can be used by a patient to be examined during a video call and to submit a non-emergent-examination for review by their healthcare provider.

Rx-only use: Steth IO Spot may be prescribed by a licensed medical provider to monitor medical conditions that require the use of a stethoscope.

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
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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 submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

StratoScientific, Inc.
19125 North Creek Pkwy. #120
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Tel: +1.425.260.0729

Company Contact: Mahesh Mulumudi
CEO and President

Contact Person: Meritxell Martinez
Associate Regulatory Consultant
Contact Email: meri@fdaecopy.com
Date Prepared: March 1st, 2022

II. DEVICE

Name of Device:	Steth IO Spot
Classification Name:	Electronic Stethoscope
Classification Panel:	Cardiovascular
Regulation:	21 CFR §870.1875
Regulatory Class:	Class II
Product Classification Code:	DQD

III. PREDICATE AND REFERENCE DEVICE

Primary Predicate Manufacturer:	Eko Device, Inc.
Primary Predicate Trade Name:	Eko CORE
Primary Predicate 510(k):	K200776
Reference Device Manufacturer:	StratoScientific, Inc.
Reference Device Trade Name:	Steth IO
Reference Device 510(k):	K160016

IV. DEVICE DESCRIPTION

The Steth IO Spot is an acoustic device with an integrated microphone that collects biological sounds. Steth IO Spot attaches to the lightning port/USB-Type C (Universal Serial Bus Type C) port of the smartphone and can be utilized to auscultate patients during physical examination. The sound is then analyzed by the Steth IO Spot software telemedicine application (app) installed on the smartphone. This analysis enables a healthcare provider to identify sounds and from targeted areas of interest that may be present. A web portal (i.e., the Steth IO Portal) may also be used to access recorded patient data and to hold telemedicine calls.

The Steth IO Spot device has two main components:

- Steth IO Spot device: The Steth IO Spot device is capable of transmitting your heart, lung or other biological sounds to the mobile device. This device needs to be connected to the smartphone's lightning port/USB-Type C port.
- Steth IO Spot Software (Telemedicine App): The Steth IO smartphone application software

performs real-time analysis to hear the sounds using headphones. The app is available for download from a designated software repository.

A chest piece, consisting of a bell and diaphragm, and an integrated microphone is placed on the patient and the sound is transmitted to a smartphone via lightning port/USB-C port. The device is capable of recording sound data, allowing the patient-user at one location to share audio data with their healthcare provider on site or at a different location on the network.

V. INDICATIONS FOR USE

The Steth IO Spot is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data, whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. Steth IO Spot is intended for use on individuals undergoing physical examination. The Steth IO Spot is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis or emergency use.

OTC use: Steth IO Spot can be used by a patient to be examined during a video call and to submit a non-emergent-examination for review by their healthcare provider.

Rx-only use: Steth IO Spot may be prescribed by a licensed medical provider to monitor medical conditions that require the use of a stethoscope.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The following characteristics were compared between the subject device and the predicate device:

	Steth IO Spot	Eko CORE – K200776
Indications for Use	The Steth IO Spot is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data, whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. Steth IO Spot is intended for use on individuals undergoing physical examination. The Steth IO Spot is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis or emergency use. OTC use: Steth IO Spot can be used by a patient to be examined during a video call and to submit a non-emergent-examination for review by their healthcare provider.	The Eko CORE is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. Eko CORE is intended for use on pediatric and adult patients. The Eko CORE is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis.

	Rx-only use: Steth IO Spot may be prescribed by a licensed medical provider to monitor medical conditions that require the use of a stethoscope.	
Standards Met	IEC 60601-1:2005/A1:2012/A2:2020 IEC 60601-1-2:2015 IEC 60601-1-11:2015 IEC 62304:2006/A1:2016 ISO 14971:2019 ASTM D 4169-16 ISO 15223-1:2016 IEC 62366-1:2015	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11
Device Classification	DQD: Electronic stethoscope	DQD: Electronic stethoscope
Prescribed	Rx and OTC	Rx and OTC
Classification	Class II	Class II
Stethoscope Type	Electronic stethoscope with attachment to smartphone via lightning port/USB-C port	Attachment to an analog stethoscope (Core)
User Interface	Steth IO Spot hardware device Mobile App/Web Portal	On/Off Power button Volume adjustment LED status indicator Mobile App
Analog/Digital Interoperability	Not applicable	Yes
Connectivity to mobile phone	Wired connection via lightning port/USB-C port	Bluetooth
Sound Amplification	Yes	Yes
Record and Playback Sounds	Yes	Yes
Data Transfer to Compatible Computing Platform	Yes	Yes

VII. PERFORMANCE DATA

The following performance data were provided in the support of this submission:

Performance Testing

- Functional
    - Heart Rate Accuracy Test, side-by-side comparison test with predicate device and FDA-cleared gold standard (EKG). The Steth IO Spot successfully met the acceptance criteria of a concordance correlation coefficient of substantial strength (0.95 – 0.99). The Steth IO Spot's method to evaluate heart rate had a high concordance correlation with the heart rate measured by the Eko CORE (predicate device) and EKG (gold standard). Thus, the Steth IO Spot is considered to be similar to the predicate device in terms of heart rate

measurement performance.

- Frequency Audio Response Test, side-by-side comparison test with predicate device at a response beyond 2000 Hz. The Steth IO Spot performed better than the Eko CORE (predicate device) with an overall amplitude (dB) of the signal registered by the Steth IO Spot being higher than that registered by the Eko CORE. Moreover, Steth IO Spot's frequency response curve was smooth, and free of undesirable spikes and dips. The heart and lung sounds of clinical interest fall within the range for which testing was conducted. Therefore, the Steth IO Spot performs equivalently to the EKO Core device in regards to audio frequency response performance.

- Human factors usability testing was conducted per IEC 62366-1 to evaluate that the intended users of the Steth IO Spot device are able to achieve its intended use with the help of the instructions for use. Two separate studies were conducted. One study evaluated healthcare professional users in their intended use environment (e.g., hospital setting, office setting, etc.) and the other study evaluated patient-users (i.e., lay-users) in the home setting. Overall, the Steth IO Spot successfully met the acceptance criteria and all users were able to successfully achieve the intended use of the device when given the appropriate instructions for use.

Biocompatibility Testing

The main patient-contacting components of this device are the diaphragm and retainer ring, which are off-the-shelf components that are identical to the ones used in the previously-cleared reference device (K160016) as well as other stethoscopes in the market. No biocompatibility testing was required to demonstrate substantial equivalence.

Electrical safety and electromagnetic compatibility (EMC)

The Steth IO Spot is an active device used in conjunction with the user's own smartphone. The following ES/EMC tests were conducted per the respective international standards:

- IEC 60601-1:2005/A1:2012/A2:2020 General electrical safety testing
- IEC 60601-1-2 Edition 4.0 2014-02 EMC testing
- IEC 60601-1-11: 2015 Requirements for medical devices in home healthcare environment

Software Verification and Validation Testing

The Steth IO Spot Software is developed and tested in compliance with IEC 62304.

VIII. CONCLUSIONS

Based on a comparison of technological characteristics, indications for use, and performance data, it can be concluded that the proposed Steth IO Spot is substantially equivalent to the predicate device.