March 23, 2021

MyHomeDoc Ltd.
℅ Jonathan Kahan
Partner
Hogan Lovells US LLP
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K202483
Trade/Device Name: MyHomeDoc
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, FLL, DQA, ERA
Dated: March 23, 2021
Received: March 22, 2021

Dear Jonathan Kahan:

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,

for LT Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

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)*
K202483

Device Name
MyHomeDoc device

Indications for Use *(Describe)*

The MyHomeDoc device, combined with a smartphone application, is a multiple-sensor device that is intended to measure, record, and transmit the recorded data of auscultation sound of human body, human body temperature, oxygen saturation (SpO_2) and pulse rate, and images of an examined body part.

MyHomeDoc device is intended for use by adult lay users in a non-clinical environment. MyHomeDoc application enables counseling with the physician and transmission of the information over an IP network.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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:

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Traditional Premarket Notification Submission – 510(k)
MyHomeDoc device
510(k) Number K202483

Date Prepared: August 28, 2020

I. SUBMITTER

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II. DEVICE
Name of Device: MyHomeDoc device
Common or Usual Name: MyHomeDoc device
Classification Name: Oximeter, Clinical Electronic Thermometer, Oximeter and Otoscope
Regulatory Class: II
Product Code: DQD, FLL, DQA, ERA

III. PREDICATE DEVICE
MyHomeDoc Ltd. believes that the MyHomeDoc device is substantially equivalent to the following predicate devices:

- **Pulse Oximeter**- PulseOx 5500 Finger Device, manufactured by SPO Medical Ltd cleared under K040178, Classification name: Oximeter, Product code: DQA, Regulation: 21 CFR 870.2700

- **Stethoscope**- Tyto Stethoscope manufactured by Tyto care Ltd. cleared under K160401, Classification name Electronic stethoscope, Product code: DQD, Regulation: 21 CFR 870.1875

- **Thermometer**- Braun No Touch + Forehead NTF3000 Thermometer, manufactured by Kaz USA, Inc, cleared under K163516, Classification: Clinical Electronic Thermometer, Product code: FLL, Regulation: 21 CFR 880.2910

In addition, the following reference device is used in this 510(k):

- Electronic Stethoscope Model 3200, manufactured by 3M Littman, cleared under K101834, Classification name Electronic stethoscope, Product code: DRG, Regulation: 21 CFR 870.2910

IV. DEVICE DESCRIPTION

The MyHomeDoc device is a home use device. The device is comprised of a handheld unit that connects with a smartphone and a dedicated smartphone software application that runs on the user's personal smartphone An API is defined to enable healthcare providers to communicate with the device.

The Device enables user's examination at home with or without the guidance of a remote physician. It also enables guidance and data examination by a remote physician over an IP network. The Smartphone Application controls the Handheld Unit's functionality and processes and displays the collected data.

V. INDICATIONS FOR USE

The MyHomeDoc device, combined with a smartphone application, is a multiple-sensor device that is intended to measure, record, and transmit the recorded data of auscultation sound of human body, human body temperature, oxygen saturation (SpO2) and pulse rate, and images of an examined body part.

MyHomeDoc device is intended for use by adult lay users in a non-clinical environment. MyHomeDoc application enables counseling with the physician and transmission of the information over an IP network.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE AND REFERENCE DEVICE

The MyHomeDoc device is substantially equivalent to its predicate devices.

MyHomeDoc device intended use combines the indications of the cleared predicate devices.

The MyHomeDoc device, like the Tyto Stethoscope, is intended for adults to record sounds from adult and pediatric patients' heart and lungs and abdomen in a home environment. Like the PulseOx 5500 predicate, the MyHomeDoc device is intended for saturation and pulse rate measurements. Similar to the Braun Forehead NTF3000 thermometer, MyHomeDoc device is intended for body temperature determination.

The MyHomeDoc device has similar technological characteristics as the predicate Tyto Stethoscope in that it records and wirelessly transmits the patient's data to the care provider at a different location. Both devices contain software guidance that instructs the user where to place the sensor to measure the auscultation signal. An additional similarity is that the Tyto includes a class I otoscope as well.

The temperature sensor in the MyHomeDoc device is equivalent to its predicate in that both are contact/non-contact IR sensors that measure temperature from the center of the forehead. Both devices then convert this temperature to the oral equivalent and display this temperature in Fahrenheit or Celsius. While the thermometers have the same accuracy, there are slight differences in regards to the measurement range, but as the subject device has a greater range, this does not raise any questions. The company has performed testing demonstrating the performance of the thermometer over this temperature range.

The pulse oximeter in the MyHomeDoc device and the predicate are equivalent in that they both measure change in light intensity at 660 and 880 nm. Both devices perform spot measurement of oxygen saturation and pulse rate at the patient's fingertip. The measurement methods slightly differ in that the predicate measures the transmitted signal, while the subject device assesses the reflected signal.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination:

- **Biocompatibility evaluation** in compliance with ISO 10993-1.

- **Cleaning, Packaging**
  Cleaning validation testing, transportation and use life calculation of the MyHomeDoc device was performed to demonstrate compliance with the relevant standards. All tests were successfully completed.

- **Performance Testing**
  Performance testing included the following:

Name of test	Test description
Thermometer	
Thermometer performance & accuracy testing	Test in compliance to ASTM E1965−98.The MyHomeDoc device met all acceptance criteria. The results of this test demonstrate that the difference between the IR readings (the "Direct mode") and the Black body is less than 0.3°C
ASTM E1965−98 Thermometer	The test tables demonstrate compliance of the MyHomeDoc Thermometer component with ASTM E1965-98, Standard Specification for Infrared Thermometers for Intermittent Determination of Patient Temperature
MyHomeDoc Device vs. Braun Predicate Device for Oral Equivalence Test Report	The difference between MyHomeDoc and the Brown NTF3000 predicate device was less than or equal to 0.4°C in a 81users. Therefore, the MyHomeDoc device met the acceptance criteria.
Pulse oximeter	
SpO2 verification protocol and report	The MyHomeDoc device met all acceptance criteria. - displayed SpO2 value for each simulator value. - MyHomeDoc measurements of monotonic increasing/decreasing values are monotonic and align within the 20% range.
Pulse rate verification	MyHomeDoc device measured pulse results between 30BPM to 250BPM. MyHomeDoc device met the acceptance criteria.
Pulse Oximeter Hypoxia Protocol and Report	The pulse oximeter hypoxia test performed in order to validate the MyHomeDoc device SpO2 measurements. The MyHomeDoc device met all acceptance criteria.
Stethoscope	
Stethoscope Test Report	The MyHomeDoc device and the Littman predicate stethoscope where evaluated. MyHomeDoc devices used in the test met the acceptance criteria.
Otoscope	
Otoscope Test Report	Line-pair separation test, Color differentiation and Illumination flux were evaluated. MyHomeDoc devices used in the test met the acceptance criteria
Otoscope-gold standard vs. MyHomeDoc ear test comparison report	MyHomeDoc images were cleared allowing clinical evaluation, Landmarks of the ear were easily identified and the physician subjective assessment was positive. Therefore, the MyHomeDoc device met the acceptance criteria and MyHomeDoc images are equivalent to those

Name of test	Test description
	of the gold standard.

All tests met the predefined acceptance criteria.

- **Software Validation**
  The MyHomeDoc software level of concern is moderate. Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices".

- **Electrical Safely and EMC**
  Electrical Safety per IEC 60601-1 and Electromagnetic compatibility (EMC) per IEC 60601-1-2 and IEC 60601-1-6 were conducted on the MyHomeDoc device. In addition, the system complies with IEC 60601-1-11, IEC 62471 First edition, ISO 80601-2-61 and IEC 60529, wireless coexistence testing.

- **Usability testing**
  Usability study was conducted to evaluate the use-related safety and effectiveness of the MyHomeDoc when used by lay-user via observational data, knowledge task data, and interview data. The purpose of the current study is to demonstrate that MyHomeDoc device can be used by the intended users for the intended uses and under the expected use conditions without serious use errors or problems.

VIII. CONCLUSIONS

The MyHomeDoc device was determined to be substantially equivalent to the predicate devices.