December 18, 2019

Hefei Mintti Medical Technology Co., Ltd. China
Shengsheng Cai, General Manager
C309, National University Science Park, 602 Huangshan Road,
High-tech Zone, Hefei, 230088, CHINA

Re: K191667
Trade/Device Name: Electronic Stethoscope – smartho-D2
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: November 20, 2019
Received: November 26, 2019

Dear Shengsheng Cai:

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,

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)*
K191667

Device Name
Electronic Stethoscope - smartho-D2

Indications for Use *(Describe)*
The Electronic Stethoscope is intended for the detection and amplification of sounds from the heart, lungs and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment 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

Prepared in accordance with the requirements of 21 CFR Part 807.92

1. Submitter:

Hefei Mintti Medical Technology Co., Ltd. China

C309, National University Science Park, 602Huangshan Road, High-tech Zone, Hefei City, Anhui Province, 230088, China
Tel.: +86 0551-636388104

Contact Person:

Shengsheng Cai

Prepare date:

December 16, 2019

2. Device name and classification:

Device Name: Electronic Stethoscope

Models: smartho-D2

Classification Name:

21 CFR 870.1875 Stethoscope, Electronic

Product code: DQD

Regulatory Class: Class II

3. Reason for Submission

New Application.

4. Predicate Device(s):

3M Health Care, 3M™ Littmann® Electronic Stethoscope Model 3200 cleared under K083903

5. Device Description:

The Mintti Electronic Stethoscope, model smartho-D2 is a healthcare device that picks up sounds of the heart, lungs and other internal organs with the use of selective frequency ranges from 10-2000Hz. After amplification and filtering, the sounds are transferred to the user's ears via an wired-connected headset.

The user interface includes a 5-button keypad and an 1.3’ OLED display with a blue back-light. Sound processing is carried out with the aid of a digital signal processor.

The smartho-D2 does not incorporate any off-the-shelf (OTS) software, and it incorporates embedded software which controls all the features of the product, including sound capture, digital signal processing, volume control, OLED display and Bluetooth function.

The smartho-D2 operates on a certificated rechargeable 3.7V/2000mAh lithium ion battery.

6. Indications for Use:

The Electronic Stethoscope is intended for the detection and amplification of sounds from the heart, lungs and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment for medical diagnostic purposes only.

7. Predicate Device Comparison

In comparison to the predicate device, the subject device has the same intended use, similar product design, and performance safety as the predicate device.

Please refer to the following table that notes differences between the subject device and predicate device. All the differences do not affect the basic design principle, usage, effectiveness and safety of the subject device. No new questions are raised regarding effectiveness and safety.

Table 1 Specific Comparison to Predicate

ITEM	**Proposed Device** smartho-D2	**Predicate Device** 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200	**Comment**
Regulatory			
Classification	Stethoscope, Electronic	Stethoscope, Electronic	Same
Regulation	Class II, 21 CFR 870.1875	Class II, 21 CFR 870.1875	Same
Product code	DQD	DQD	Same
Indications for Use			
Indications for Use	The Electronic Stethoscope is intended for the detection and amplification of sounds from the heart, lungs, and other internal organs with the use of a selective frequency. It can be used on any person undergoing a physical assessment for medical diagnostic purposes only.	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 selective frequency ranges.It can be used on any person undergoing a physical assessment.	Different
Contraindications	None	None	Same
Power Supply			
Source Type	Battery	Battery	Same
Battery Type	A rechargeable 3.7V/2000mAh lithium ion battery	One AA alkaline, lithium, or NiMH battery(rechargeable).	Different
Battery Operation Time	48 Hours	50-60 Hours	
Technical Specifications			
Binaural headset	YES	YES	Same
Chest-piece	YES	YES	Same
Sound	Digital signal processor	Digital signal processor	Same

processing			
Display Screen	1.3' Color OLED	LCD	Different
Low Battery Indicator	YES	YES	Same
Automatic Power Off	No	YES	Different
Volume Control	1-4 level	1-9 level	
Sound Amplifier	Amplifies up to 100X	Amplifies up to 24X	Different
Signal Sampling Rate	8 kHz	4 kHz	Different
Frequency Response	20 -2000Hz Heart Sound Mode:20-500Hz Lung Sound Mode: 200-2000Hz	Bell (20-1000 Hz) Diaphragm (20-2000 Hz) "Extended Range" (50-500 Hz)	Different
Intuitive keypad	NO	No	Same
A/P Chest key	No	No	Same
Direct Listening	Only transferred via headset	Littmann® Model 3200 allows direct listening to sounds in real time through the device's attached binaurals.	Different
Recording and Playback	Not on the device itself	Yes – stores twelve (12) 30 second tracks on device	Different
Wireless Technology	Yes–uses Bluetooth® at 2.4 GHz	Yes–uses Bluetooth® at 2.4 GHz	Same
Ambient & Frictional Noise Reduction Technology	YES	YES	Same

As seen in the comparison tables, the subject and predicate devices have similar design features and performance specifications. The differences between the subject and predicate devices do not raise different questions of safety or effectiveness. Moreover, as demonstrated in the bench testing, the different indications and technological characteristics do not affect the safety and effectiveness of the smartho-D2 Electronic Stethoscope.

8. Performance Testing:

Performance data includes "Non-Clinical Data" and "Clinical Data". Summary of the data provided is below:

Non-Clinical Data:
The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the smartho-D2 Electronic Stethoscope was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The worst case of the whole system is considered tissue-contacting for a duration of less than 24 hours. And Cytotoxicity, Skin Sensitization and Skin Irritation tests were conducted.

Reprocessing: Cleaning and Disinfection

The sterilization and shelf life information provided are acceptable because the subject devices are non-sterile devices. The validation testing results for cleaning and disinfection of the subject devices are adequate and acceptable.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the smartho-D2 Electronic Stethoscope device, consisting of all the modules and accessories in the system. The system complies with IEC 60601-1:2012 *Medical electrical equipment Part 1: General requirements for basic safety and essential performance* for safety, IEC 60601-1-11: 2010 *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*, and the 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* standard for EMC.

Bench Testing
Bench testing was conducted on the smartho-D2 Electronic Stethoscope device, consisting of all the accessories in the system, which demonstrates that the smartho-D2 can perform over its intended range of operation (10-2000Hz). Comparative performance testing submitted in the 510(k) demonstrated the two devices perform in a substantially equivalent manner.

Software Verification and Validation Testing
Software documentation including verification & validation was provided in accordance with FDA Guidance: *Guidance for the* Content *of Premarket Submissions for Software Contained in Medical Devices* for software with a moderate level of concern.

Risk Analysis
A risk analysis was conducted in accordance with ISO 14971: 2007 – Medical devices — Application of risk management to medical devices.

Wireless Function Testing

The wireless coexistence test is conducted per the FDA Guidance *Radio Frequency Wireless Technology in Medical Devices* dated on August 14, 2013 to demonstrate no effect on the safe and effective use of the device.

Clinical data:

No animal or clinical testing was submitted in this 510(k).

9. Substantial Equivalence Conclusion:

Differences between the indications for use and technological characteristics of the subject device compared to the predicate do not raise different questions of safety and effectiveness. The performance of the device is supported by performance testing, and risk management activities. The Mintti smartho-D2 Electronic Stethoscope is Substantially Equivalent (SE) to the 3M™ Littmann® Electronic Stethoscope Model 3200 cleared by K083903.