



August 17, 2018

IMEDIPLUS INC.
Shirley Lai
Regulatory Specialist
2F, 12, Shengyi Rd.Sec.2
Chupei City, Hsinchu County 30261 Taiwan (R.O.C.)

Re: K173663
Trade/Device Name: Electronic Stethoscope DS3011A
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: July 16, 2018
Received: July 18, 2018

Dear Shirley Lai:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

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,

Shawn W.
Forrest -A

Digitally signed by Shawn W. Forrest -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People,
0.9.2342.19200300.100.1.1=1300403341,
cn=Shawn W. Forrest -A
Date: 2018.08.17 16:40:17 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number (if known)
K173663

Device Name
IMEDIPLUS Electronic Stethoscope DS3011A

Indications for Use (Describe)

The IMEDIPLUS Electronic Stethoscope DS3011A is intended for the detection, amplification and recording of sounds from the heart, lungs, anterior and posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with selective frequency ranges. And the stethoscope chest-piece is designed for use with child, adolescent and adult patients. It is used for any subject undergoing a physical examination and intended only for medical diagnostic purposes in clinic or hospital.

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.

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IMEDIPLUS INC.

Deficiency Reply Electronic Stethoscope DS3011A

Section 5

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File Name: 018_510(k)Summary

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510(k) Summary

The Assigned 510(k) Number: K173663/S002
Date Prepared: August 17, 2018.

I. Submitter Information:

Submitter:

IMEDIPLUS INC.

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Date Prepared: August 17, 2018.

II. Predicate Device

Predicate Device:


IMEDIPLUS Electronic Stethoscope DS301.

Reference Device:

3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200

Table 1 Predicate Device Identification

	Device Name	Manufacturer	Model	510(k) Number
Candidate Device	IMEDIPLUS Electronic Stethoscope DS3011A	IMEDIPLUS INC.	DS3011A	K173663
Predicate Device	IMEDIPLUS Electronic Stethoscope DS301	IMEDIPLUS INC.	DS301	K160023
Reference Device	3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200	3M COMPANY	3M 3200	K083903

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III. Device

Table 2 Common Name and Classification

No.	Product Code	Device	Regulation Section	Classification	Panel
1	DQD	Stethoscope, Electronic	870.1875	II	Cardiovascular

IV. Device Description


When you turn on the IMEDIPLUS Electronic Stethoscope DS3011A for the first time, the IMEDIPLUS Electronic Stethoscope DS3011A in your hand requires your setting password for the security. Your authorization to operate this handheld electronic stethoscope is necessary for the operation.

The IMEDIPLUS Electronic Stethoscope DS3011A picks up the sounds from the heart, lung, anterior/posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs from a patient's body. When picking up the sounds, the phonogram of sounds could simultaneously display after pushing the button 'OK' or 'REC' for recording. When you auscultate with DS3011A, the sounds are conducted simultaneously to the user's ears bilaterally by active speaker embedded at the bottom of the IMEDIPLUS Electronic Stethoscope DS3011A. At the meantime, sound processing is operated with the aid of a digital signal processor. The IMEDIPLUS Electronic Stethoscope DS3011A could identify the recording number by 1-D barcode reader, indicate the sound location by intuitive keypad, and record the sounds from different sites.

The one-hand user interface includes a full-color OLED display, an intuitive keypad at the anterior part, a barcode reader at the posterior part, a chest-piece at the superior part, a tube connector for output of sounds at the inferior part, and a recording button at the left part.

After opening the Electronic Stethoscope DS3011A with your setting password and connection with a wireless device by Bluetooth, the IMEDIPLUS Electronic Stethoscope DS3011A could transmit digital data of recorded sounds under the operation of IMEDIPLUS DS3011A_DM Software (DS3011A Data Management) installed in the connected device. The effective range of transmission by Bluetooth will be influenced when some objects blocking between the IMEDIPLUS Electronic Stethoscope DS3011A and the connected device. (such as wall, human, big objectives as barrier) Reducing the distance or allowing the line of sight between the IMEDIPLUS Electronic Stethoscope DS3011A and the connected device will improve the connection by Bluetooth.

The IMEDIPLUS DS3011A_DM Software (DS3011A Data Management) will only operate under the user's authorization with the seething password. The IMEDIPLUS DS3011A-DM Software (IMEDIPLUS DS3011A-Datamanagement Software) installed in mobile device provides the users to connect with the IMEDIPLUS Electronic Stethoscope DS3011A, receive the recorded data of sounds, storage the data, display the phonograms, and replay the recorded

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audio data with the speaker of effective frequency range from 20 to 1000Hz.

The IMEDIPLUS Electronic Stethoscope DS3011A could also exchange audio data with an external personal computing device by micro SD card. Every single audio file stored in the micro SD card was labeled with the user's ID, recording number and indicated position. The IMEDIPLUS Electronic Stethoscope DS3011A does not incorporate any other off-the-shelf (OTS) software. The recorded audio data only can be replayed by the IMEDIPLUS Electronic Stethoscope DS3011A, the IMEDIPLUS Electronic Stethoscope DS301, and the IMEDIPLUS DS3011A_DM Software (DS3011A_Data Management) installed in the mobile device with the speaker of effective range from 20 to 1000Hz. The IMEDIPLUS Electronic Stethoscope DS3011A operates on one (1) NP-120 lithium battery with an included power management system to prolong the battery life.

The associated accessories include:

- Rechargeable Lithium-ion Battery.
- Battery charger which includes adaptor and charger.
- Micro SD card for exchanging audio data.


V. Indication for Use

The IMEDIPLUS Electronic Stethoscope DS3011A is intended for the detection, amplification and recording of sounds from the heart, lungs, anterior and posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with selective frequency ranges. And the stethoscope chest-piece is designed for use with child, adolescent and adult patients. It is used for any subject undergoing a physical examination and intended only for medical diagnostic purposes in clinic or hospital.

VI. Comparison of Technology Characteristics between the Predicate Devices (The IMEDIPLUS Electronic Stethoscope DS3011A reference with 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200 and predicate the IMEDIPLUS Electronic Stethoscope DS301)

(A) Same technological elements among these 3 candidates (Table 3)


- (a) Binaural headset – send sounds to user's ears.
- (b) Chest-piece – pick up sounds from patient's internal organs.
- (c) Sound amplifier – amplify the sounds from chest-piece.
- (d) Battery – power the device.
- (e) Digital signal processor – sound processing.
- (f) Display – show the operation information.
- (g) Keypad – control and setup the device.
- (h) Detect and display heart rate – monitor patient's heart rate.
- (i) Record – record a sound track.
- (j) Playback–playback a sound track.
- (k) Filter Selection – select certain mode of filter for clinical auscultation, including B/ D/ W mode.
- (l) Sound amplification level adjustment – control the level of sound amplification.

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(m) Monitor Battery level – indicate the battery level.

Table 3 Same Technological Elements among These 3 Candidates


Items	Comparison Items	Candidate Device DS3011A	Reference Device 3M 3200 (K083903)	Predicate Device DS301 (K160023)
1	Regulatory			
	Regulatory No	870.1875	870.1875	870.1875
	Classification	Class II	Class II	Class II
2	Power Source			
	Batteries Enclosed	One NP-120 Lithium battery	One AA battery	One NP-120 Lithium battery
	Battery Life	24 Hours	50-60 Hours	24 Hours
	Special Adaptors	Yes	No	Yes
3	Features			
	Binaural headset	Same	Same	Same
	Chest-piece Technology	Single Sided	Single Sided	Single Sided
	Chest-piece Weight	69g	98g	69g
	Clinical Area	Auscultation	Auscultation	Auscultation
	Diaphragm Diameter	4.1cm	5.1cm	4.1cm
	Diaphragm Material	Silicon	Polyurethane-Coated Silicone	Silicon
	Ear-tips Type	Soft Sealing	Soft Sealing	Soft Sealing
	Headset Material	Brass alloy to electroplate	Wide diameter aerospace alloy / Anodized aluminum	Brass alloy to electroplate
	Length	77 cm	69 cm	77 cm
	Net Weight	304 g	185 g	304 g
	Tube Color	Black 、 Burgundy 、 Navy Blue	Black 、 Burgundy 、 Navy Blue	Black 、 Burgundy 、 Navy Blue
4	Intended Use			
	Intended Use	The IMEDIPLUS Electronic Stethoscope DS3011A is intended for the detection, amplification and recording of sounds from the heart, lungs, anterior and posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with selective frequency ranges. And the stethoscope chest-piece is designed for use with child, adolescent and adult patients. It is used for any subject undergoing a physical examination and intended	The 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.	The IMEDIPLUS Electronic Stethoscope DS301 is intended for the detection, amplification and recording of sounds from the heart, lung, anterior/posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with use of selective frequency ranges. And the stethoscope chest-piece is designed for use with child, adolescent and adult patients. It is used for any subject

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		only for medical diagnostic purposes in clinic or hospital.		undergoing a physical examination and intended only for medical diagnostic purposes in clinic or hospital.
5	Functional			
	Screen	OLED 1.46" Full Color	LCD Monochrome	OLED 1.46" Full Color
	Barcode Reader	Yes	No	Yes
	Three Filter Modes	Yes	Yes	Yes
	Frequency Range of Filter Mode	Bell (20-200 Hz) \ Diaphragm (100-500 Hz) and Wide (20-1000Hz)	Bell (20-200 Hz) \ Diaphragm (100-500 Hz) and Extend range (20-2000 Hz)	Bell (20-200 Hz) \ Diaphragm (100-500 Hz) and Wide (20-1000Hz)
	Human Machine Interface	One-hand user interface for patient's ID scanning, auscultation position selection, recording, and function selection.	Yes	One-hand user interface for patient's ID scanning, auscultation position selection, recording, and function selection.
	Recording Number of the sound track	Yes	No	Yes
	Recording the Organ and Position of the Sound Track	Yes	No	Yes
Dip	Software Comparison			
	Heart Rate Detection	Yes	Yes	Yes
	Heart Rate Display	Yes	Yes	Yes
	Recording the Sound Track	Yes	Yes	Yes
	Playback the Sound Track	Yes	Yes	Yes
	Volume Control	Yes	Yes	Yes
	Volume Control Scale	Yes 1-10 level	Yes 0-9	Yes
	Amplification	Yes 24 times	Yes 24 times	Yes 24 times
	Filter mode selection	Yes, Bell, Diaphragm, and Wide modes	Yes Bell, Diaphragm and Extend Modes	Yes, Bell, Diaphragm, and Wide modes
	Automatic turn-off	Yes	Yes	Yes
	Monitor the battery level	Yes	Yes	Yes
	Password Setting	Yes, The user needs to enter	No	No

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		the password for the operation of the device		
	Display the Phonogram	Yes, Display the synchronized phonogram on the screen during the auscultation with the IMEDIPLUS Electronic Stethoscope DS3011A	No	No
	Software of the Connected Device	Yes, IMEDIPLUS DS3011A-DM software (DS3011A DataManagement software) (1) Receive and storage the data of sound tracks (2) Display the phonogram of the sound tracks (3) Reply the audio data in the connected device installed with IMEDIPLUS DS3011A-DM software but this software could not operate the IMEDIPLUS Electronic Stethoscope DS3011A to replay the sound track from the connected device.	Yes, 3MTM Littmann® Zargis StethAssist™ Heart and Lung Sound Visualization Software	No
7	Function of Data Transfer and the Interface			
	Data Transfer of the Recorded Sound Tracks	Yes, Micro SD card and Bluetooth (1) Micro SD card, (Permits the data exchange from the electronic stethoscope to the personal computer) (2) Bluetooth, (transmits the audio data from the stethoscope to the connected device)	Yes Bluetooth Permits the data exchange from the electronic stethoscope to the personal computer	Yes Micro SD card Permits the data exchange from the electronic stethoscope to the personal computer
	Capable of Storing Data and Latest sound tracks for playback	Save up to 600 10-second sound tracks; Latest 50 sound tracks for playback.	Save up to twelve 30-second sound tracks; Latest 12 sound tracks for playback.	Save up to 999 10-second sound tracks; Latest 15 sound tracks for playback.
8	Service and Occupation			

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	Warranty Period	2 Years	2 Years	2 Years
	Occupation	Anesthesiologist, Cardiologist, Emergency Physician, EMT/EMS, Family Practitioner, Internist, Medical Assistant, Medical Student, Nurse, Nursing Student, Pediatrician, Physician, Respiratory Specialist, Teacher/Professor/Instructor, and Veterinarian.	Anesthesiologist, Cardiologist, Emergency Physician, EMT/EMS", Family Practitioner, Internist, Medical Assistant, Medical Student, Nurse, Nursing Student, Pediatrician, Physician, Respiratory Specialist, Teacher/Professor/Instructor, and Veterinarian.	Anesthesiologist, Cardiologist, Emergency Physician, EMT/EMS, Family Practitioner, Internist, Medical Assistant, Medical Student, Nurse, Nursing Student, Pediatrician, Physician, Respiratory Specialist, Teacher/Professor/Instructor, and Veterinarian.
	Teaching Accessories Included	User manual	CD-ROM User manual	User manual

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(B) Comparison between the Electronic Stethoscope DS3011A and the reference device, the 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200

(a) The differences between these two devices: (Table 4)

- (1) 1D Barcode reader – identify the user's ID and recording number.
- (2) Micro SD card – storage and exchange for sound tracks.
- (3) Organ position indication – indicate the auscultated organ.
- (4) Auscultation position indication – used to indicate the auscultation position of organ.
- (5) Intuitive keypad – select the organ position between heart and lung during auscultation.
- (6) A/P CHEST Key – switch the organ position between “Anterior Chest” and “Posterior Chest”.
- (7) Password – the user needs to enter the password to access device.
- (8) Phonogram display for real time monitoring sound wave.

(b) The same elements between these two devices: (Table 4)

- (1) Both of these connect with Bluetooth.
- (2) Binaural headset – send sounds to user's ears.
- (3) Chest-piece – pick up sounds from patient's internal organs.
- (4) Sound amplifier – amplify the sounds from chest-piece.
- (5) Battery – power the device.
- (6) Digital signal processor – sound processing.
- (7) Display – show the operation information.
- (8) Keypad – control and setup the device.
- (9) Detect and display heart rate – monitor patient's heart rate.
- (10) Record and playback – record and playback a sound track.
- (11) Select filter – select certain mode of filter for clinical auscultation, including B/ D/ W mode.
- (12) Sound amplification level adjustment – control the level of sound amplification.
- (13) Monitor battery level – indicate the battery level.


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Table 4 Same and Differences Technological Elements between DS3011A and 3M 3200

Features	Candidate Device DS3011A	Reference Device 3M 3200	Same/Different
1D Barcode reader	Yes	No	Different
Micro SD card	Yes	No	Different
Organ position indication	Yes	No	Different
Auscultation position indication	Yes	No	Different
Intuitive keypad	Yes	No	Different
A/P CHEST Key	Yes	No	Different
Password	Yes	No	Different
Phonogram display on the screen	Yes	No	Different
Wireless connection by Bluetooth	Yes	Yes	Same
Binaural headset	Yes	Yes	Same
Chest-piece	Yes	Yes	Same
Sound amplification	Yes	Yes	Same
Battery	Yes	Yes	Same
Digital signal processor	Yes	Yes	Same
Display	Yes	Yes	Same
Keypad	Yes	Yes	Same
Detect and display the heart rate	Yes	Yes	Same
Record	Yes	Yes	Same
Playback	Yes	Yes	Same
Filter selection	Yes	Yes	Same
Sound amplification level adjustment	Yes	Yes	Same
Monitor Battery level	Yes	Yes	Same

(C) Comparison between the Electronic Stethoscope DS3011A and the predicate device, the IMEDIPLUS Electronic Stethoscope DS301

(a) The differences between these two devices (Table 5)

- (1) Bluetooth interface – transmit sound data to the connected device installed with DS3011A_DM software (DS3011A Data Management).
- (2) DS3011A_DM software (DS3011A Data Management) – used to receive sound data.
- (3) Password – the user needs to enter the password to access device.
- (4) Phonogram display on the screen of IMEDIPLUS Electronic Stethoscope DS3011A – to display the phonogram while auscultating and replaying the data of audio sounds.

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(b) The same elements between these two devices (Table 5)

- (1) 1D Barcode reader – identify the user’s ID and recording number.
- (2) Micro SD card – exchange for sound tracks.
- (3) Organ position indication – indicate the auscultated organ.
- (4) Auscultation position indication – used to indicate the auscultation position of organ.
- (5) Intuitive keypad – select the organ position between heart and lung during auscultation.
- (6) A/P CHEST Key – switch the organ position between “Anterior Chest” and “Posterior Chest”.
- (7) Binaural headset – send sounds to user’s ears.
- (8) Chest-piece – pick up sounds from patient's internal organs.
- (9) Sound amplification – amplify the sounds from chest-piece.
- (10) Battery – power the device.
- (11) Digital signal processor – sound processing.
- (12) Display – show the operation information.
- (13) Keypad – control and setup the device.
- (14) Detect and display heart rate – monitor patient’s heart rate.
- (15) Record – record a sound track.
- (16) Playback–playback a sound track.
- (17) Filter selection – select certain mode of filter for clinical auscultation, including B/ D/ W mode.
- (18) Sound amplification level adjustment – control the level of sound amplification.
- (19) Monitor Battery level – indicate the battery level.


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Table 5 Same and Different Technological Elements between DS3011A and DS301

Features	Candidate Device DS3011A	Predicate Device DS301	Same/Different
Wireless connection	Yes	No	Different
Connected device software	Yes DS3011A_DM software (DS3011A Data Management software) 1.Receive the data of sounds 2.Data storage 3.Display the phonogram 4.Replay the recorded data with the spectrum of selected frequency mode 5. The audio data could be displayed with the connected device but not on the DS3011A screen.	No	Different
Password	Yes	No	Different
Phonogram display on the screen	Yes	No	Different
1D Barcode reader	Yes	Yes	Same
Micro SD card	Yes	Yes	Same
Organ position indication	Yes	Yes	Same
Auscultation position indication	Yes	Yes	Same
Intuitive keypad	Yes	Yes	Same
A/P CHEST Key	Yes	Yes	Same
Binaural headset	Yes	Yes	Same
Chest-piece	Yes	Yes	Same
Sound amplification	Yes	Yes	Same
Battery	Yes	Yes	Same
Digital signal processor	Yes	Yes	Same
Display	Yes	Yes	Same
Keypad	Yes	Yes	Same
Detect and display heart rate	Yes	Yes	Same
Record	Yes	Yes	Same
Playback	Yes	Yes	Same
Filter selection	Yes	Yes	Same
Sound amplification level adjustment	Yes	Yes	Same
Monitor battery level	Yes	Yes	Same



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Table 6 summarizes the technological characteristics among DS3011A, 3M 3200 and DS301.

Table 6 Summarized Technological Characteristics


Features	Candidate Device DS3011A	Reference Device 3M 3200	Predicate Device DS301	Same/Similar Different /New
Regulatory				
Regulatory No	870.1875	870.1875	870.1875	Same
Classification	Class II	Class II	Class II	Same
Power Source				
Source type	Battery	Battery	Battery	Same
Battery type	One Rechargeable NP-120 lithium battery	One AA battery	One Rechargeable NP-120 lithium battery	Same with DS301; different from 3M 3200.
Battery operation time	24 Hours	50-60 Hours	24 Hours	Same with DS301; different from 3M 3200.
Intended use				
Intended use	The IMEDIPLUS Electronic Stethoscope DS3011A is intended for the detection, amplification and recording of sounds from the heart, lungs, anterior and posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with selective frequency ranges. And the stethoscope chest-piece is designed for use with child, adolescent and adult patients. It is used for any subject undergoing a physical examination and intended only for medical diagnostic purposes in clinic or hospital.	3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200 is for medical diagnostic purposes only. It may be used to detect and amplify sounds from the heart, lungs, arteries, veins, and other internal organs with the use of selected frequency ranges. It can be used on any person undergoing a physical examination.	The IMEDIPLUS Electronic Stethoscope DS301 is intended for the detection, amplification and recording of sounds from the heart, lung, anterior/posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs with use of selective frequency ranges. And the stethoscope chest-piece is designed for use with child, adolescent and adult patients. It is used for any subject undergoing a physical examination and intended only for medical diagnostic purposes in clinic or hospital.	Same with DS301; similar to 3M 3200. The population is specific to children, adolescents and adults.
Functional				
Binaural headset	Yes	Yes	Yes	Same
Chest-piece	Yes	Yes	Yes	Same
Sound processing	Digital signal processor	Digital signal processor	Digital signal processor	Same
Display function	Yes	Yes	Yes	Same

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Display type	1.46" Full Color OLED	LCD	1.46" Full Color OLED	Same with DS301; different from 3M 3200. OLED is provided with the characteristics of wide view angle, high response time, high brightness, low power consumption and full color.
Filter selection	Bell (20-200 Hz) Diaphragm (100-500 Hz)	Bell (20-200 Hz) Diaphragm (100-500 Hz)	Bell (20-200 Hz) Diaphragm (100-500 Hz)	Same
	Wide (20-1000Hz)	Extend range (50-500 Hz)	Wide (20-1000Hz)	Same with DS301; different from 3M 3200. See the bench test report of audio.
Detect and display heart rate function	Yes	Yes	Yes	Same
Detect and display heart rate range	30-180 bpm	30-199 bpm	30-180 bpm	Same with DS301; different from 3M 3200.
Record function	Yes	Yes	Yes	Same
Playback function	Yes	Yes	Yes	Same
Amount of record and playback sound tracks	Save up to 600 10-second sound tracks; Latest 50 sound tracks for playback.	Save up to twelve 30-second sound tracks; Latest 12 sound tracks for playback.	Save up to 999 10-second sound tracks; Latest 15 sound tracks for playback.	Different.
Sound Amplification	Yes, Up to 24X	Yes, Up to 24X	Yes, Up to 24X	Same
Volume control	Yes	Yes	Yes	Same
Volume control level	1-10 level	1-9 level	1-10 level	Same with DS301; different from 3M 3200.
Automatic power off	Yes	Yes	Yes	Same
Monitor battery	Yes	Yes	Yes	Same

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level function				
Monitor battery level degrees	5 degrees	4 degrees	5 degrees	Same with DS301; different from 3M 3200.
Occupation	Anesthesiologist, Cardiologist, Emergency Physician, EMT/EMS, Family Practitioner, Internist, Medical Assistant, Medical Student, Nurse, Nursing Student, Pediatrician, Physician, Respiratory Specialist, Teacher/Professor /Instructor, Veterinarian.	Anesthesiologist, Cardiologist, Emergency Physician, EMT/EMS, Family Practitioner, Internist, Medical Assistant, Medical Student, Nurse, Nursing Student, Pediatrician, Physician, Respiratory Specialist, Teacher/Professor/Instructor, Veterinarian.	Anesthesiologist, Cardiologist, Emergency Physician, EMT/EMS, Family Practitioner, Internist, Medical Assistant, Medical Student, Nurse, Nursing Student, Pediatrician, Physician, Respiratory Specialist, Teacher/Professor /Instructor, Veterinarian.	Same
Sound track transfer function	Yes	Yes	Yes	Same
Sound track transfer interface	Micro SD card Bluetooth	Bluetooth	Micro SD card	(1) Micro SD card: same as DS301 (2) Bluetooth: same as 3M3200
Barcode Reader	Yes, 1D Barcode reader	No	Yes, 1D Barcode reader	Same with DS301; new for 3M 3200
Organ position indication	Yes, To indicate the organ to auscultate.	No	Yes, To indicate the organ to auscultate.	Same with DS301; new for 3M 3200
Auscultation position indication	Yes, To indicate the auscultation position of organ.	No	Yes, To indicate the auscultation position of organ.	Same with DS301; new for 3M 3200
Intuitive keypad	Yes, To choose the organ position between heart and lung during auscultation.	No	Yes, To choose the organ position between heart and lung during auscultation.	Same with DS301; new for 3M 3200
A/P CHEST key	Yes, To switch the organ position between "Anterior Chest" and "Posterior Chest".	No	Yes, To switch the organ position between "Anterior Chest" and "Posterior Chest".	Same with DS301; new for 3M 3200
Password	Yes, The user needs to enter the password	No	No	New

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	to access device			
Phonogram display on the screen	Yes, To real time monitoring sound wave.	No	No	New
Connected device software	Yes, DS3011A_DM software (DS3011A Data Management software) receive sounds data from IMEDIPLUS Electronic Stethoscope DS3011A. 1.Receive the data of sounds 2.Data storage 3.Display the phonogram 4.Replay the recorded data with the spectrum of selected frequency mode	Yes, 3M™ Littmann® StethAssist™ Heart and Lung Sound Visualization Software 1.Receive the data of sounds 2.Data storage 3.Display the phonogram 4.Replay the recorded data with the spectrum of selected frequency mode	No	New for DS301; similar to 3M 3200.

VII. Performance Data


The following performance data are provided in support of the substantial equivalence determination.

Biocompatibility

Generally, the duration of contact to the patient's skin is less than 5 minutes and less than 3-hour contact to the doctor's skin. Due to the short contact, and all the materials of contacting parts have been used in common medical device industry for years, the risk of biological hazards are assessed low based on FDA #G95-1 and ISO10993-1. It is assessed no need to perform the biocompatibility laboratory tests.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and electromagnetic compatibility reports are tested and issued by SGS Taiwan Limited. According to the test reports, the IMEDIPLUS Electronic Stethoscope DS3011A complies with the safety standard of IEC 60601-1 and the EMC stands of EN 60601-1-2, CISPR 11, IEC 60601-1-2, IEC 61000-3-2, IEC 61000-3-3, IEC 61000-4-2, IEC 61000-4-3, IEC 61000-4-4, IEC 61000-4-5, IEC 61000-4-6, IEC 61000-4-8, IEC 61000-4-11 and FCC Part 15.

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Software Verification and Validation Testing

The provided software verification and validation comply with the requirements of “guidance for the content of premarket submissions for medical devices software, May 11, 2005” and IEC/TR80002-1:2009. The level of concern of the software for this device is considered as a “moderate”, since a failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Reliability and MTBF Testing

Reliability and mean time between failure (MTBF) reports are tested and issued by DEKRA Integrated Service Technology, Inc. The reliability report shows the conditions of operation, storage and transportation environment for the IMEDIPLUS Electronic Stethoscope DS3011A. The MTBF report demonstrates the shelf life.

Battery and Photobiological Safety Testing

Battery and photobiological safety reports are tested and issued by SGS Taiwan Limited. According to the battery test reports, the battery complies with the IEC 62133:2012(Second Edition) and UN38.3 (Section 38.3 Lithium metal and lithium ion batteries in UN ST/SG/AC.10/11/Rev.5/Amend.1 Recommendation on the TRANSPORT OF DANGEROUS GOODS Manual of tests and Criteria Fifth revised edition) standards. The photobiological test report shows the IMEDIPLUS Electronic Stethoscope DS3011A complies with the IEC 62471: 2006 (First Edition) and EN 62471:2008 standards.

Usability Evaluation


The usability evaluation complies with the requirement of Clause 5.3 and 5.7.3 of the international medical device usability engineering standard, IEC 62366:2015, and IEC 60601-1-6.

Clinical Evaluation

The clinical evaluation is performed by 4 clinical doctors, who are clinically certified and qualified professionals, and three subject groups (4 children, 4 adolescents and 7 adults) are specified to conduct the clinical evaluation. The statistical analysis of the questionnaire shows that the medical equipment (IMEDIPLUS Electronic Stethoscope DS3011A) can meet the basic principles of safety and effectiveness when used in Child, Adolescent, Adult and other ethnic groups for heart, chest, intestines and neck auscultation.

Wireless Coexistence


The wireless coexistence report complies with the requirement of ANSI C63.27-2017 -American National Standard for Evaluation of Wireless Coexistence.

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Performance Testing-Bench

The bench testing report of heart rate detection function among IMEDIPLUS Electronic Stethoscope DS3011A, 3M 3200 and IMEDIPLUS Electronic Stethoscope DS301 provides a detailed analysis of the similarities and differences. The report demonstrates that the heart rate detection of IMEDIPLUS Electronic Stethoscope DS3011A is substantially equivalent to the predicate device 3M 3200 and DS301 with the condition of heart rate between 30-180 bpm.


The bench testing report of audio performance among DS3011A, DS3011A_DM software (DS3011A Data Management), 3M 3200 and DS301 provides a detailed analysis of the similarities and differences. The report demonstrates that the audio performance of IMEDIPLUS Electronic Stethoscope DS3011A and DS3011A_DM software (DS3011A Data Management) are substantially equivalent to the reference device 3M 3200 while audio frequency operates below 1 kHz. In addition, the IMEDIPLUS Electronic Stethoscope DS3011A and DS3011A_DM software (DS3011A Data Management) are substantially equivalent to the predicate device IMEDIPLUS Electronic Stethoscope DS301 for bell, diaphragm and wide frequency band mode.

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List of Standards

The IMEDIPLUS Electronic Stethoscope DS3011A conforms to the following standards:

- [1] ISO14971, *Medical devices-application of risk management to medical devices*, 2007-03-01.
- [2] IEC 62304, *Medical Device Software - Software Life Cycle Processes*, 2015-06.
- [3] AAMI TIR45, *Guidance on the use of agile practices in the development of medical device software*, 2012-08-20.
- [4] IEC/TR80002-1, *Medical device software -- Part 1: Guidance on the application of ISO 14971 to medical device software*, 2009-09-01.
- [5] AAMI ANSI IEC 62366-1, *Medical Devices - Part 1: Application Of Usability Engineering To Medical Devices*, 2015-02.
- [6] AAMI ANSI ISO 10993-1, *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*, 2009-10-15.
- [7] ISO 15223-1, *Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements*, 2016-11-01.
- [8] IEC 60601-1-2, *Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests*, 2007-03-30
- [9] IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*, 2012-12-06.
- [10] IEC 62471, *Photobiological Safety Of Lamps And Lamp Systems*, 2006-07-26.
- [11] ANSI C63.27-2017 -American National Standard for Evaluation of Wireless Coexistence. 2017-11-05.

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Performance Data Summary

The IMEDIPLUS Electronic Stethoscope DS3011A has similar safety and effectiveness profiles to that of the predicate devices, reference 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200 and predicate IMEDIPLUS Electronic Stethoscope DS301.

VIII. Conclusions

The information provided in this Abbreviated 510(k) submission shows that the IMEDIPLUS Electronic Stethoscope DS3011A is substantially equivalent to the predicate IMEDIPLUS Electronic Stethoscope DS301, cleared under K160023.