September 11, 2018

Imediplus, Inc.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, New Jersey 07041

Re: K182196
Trade/Device Name: Cardiart Electronic Stethoscope: Model DS101; Omni-Steth Electronic Stethoscope: Model Omni-Steth
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: August 11, 2018
Received: August 14, 2018

Dear Dave Yungvirt:

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,

Stephen C. Browning -S5

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)*
K182196

Device Name
Cardiart Electronic Stethoscope: Model DS101
Omni-Steth Electronic Stethoscope: Model Onmi-Steth

Indications for Use *(Describe)*
The Electronic Stethoscope DS101 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.

The Electronic Stethoscope Omni-Steth 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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510(k) Summary

510(k) Number: K182196

I. SUBMITTER:

Submitter's Name:	IMEDIPLUS INC.
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Date Prepared:	24 August 2018

II. DEVICE:

Trade Name and Model:	Cardiart Electronic Stethoscope: Model DS101 and Omni-Steth Electronic Stethoscope: Model Onmi-Steth
Common or Usual Name:	Electronic Stethoscope
Classification Number:	870.1875
Classification Name:	Stethoscope
Product Code:	DQD
Product Class:	II
Classification Panel:	Cardiovascular

III. PREDICATE DEVICE:

Device Name		Manufacturer	Classification
Primary Predicate K173663	IMEDIPLUS Electronic Stethoscope DS3011A	IMEDIPLUS INC.	DQD 870.1875
Secondary Predicate K083903	3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200	3M COMPANY	DQD 870.1875

This Secondary Predicate K083903 with the same intended use, classification and product code as the proposed device is included to support the Bluetooth wireless technology that is implemented in the subject device for which scientific methods exists to evaluate this new technology as outlined in the FDA guidance "Radio Frequency Wireless Technology in Medical Devices" (Aug 14, 2013).

IV. DEVICE DESCRIPTION

The proposed Electronic Stethoscopes Models DS101 and Omni-Steth detect and

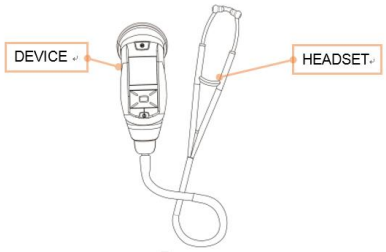
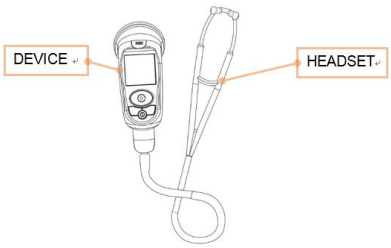
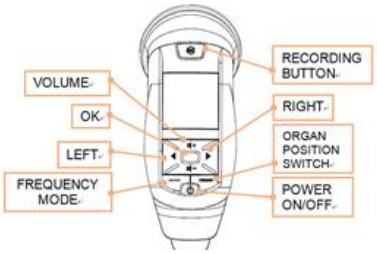
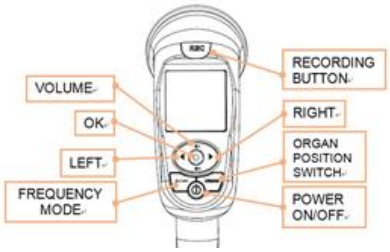
display the sounds from the heart, lungs, anterior/posterior chest, abdomen, neck, limbs, arteries, veins and other internal organs from a patient's body. After amplifying and filtering, the sounds are also sent to the user's ears bilaterally through the active speaker embedded at the bottom of the stethoscopes. Sound processing is conducted with the aid of a digital signal processor. Power to the device is provided by two AAA1.2V batteries. The one-hand operable user interface consists of a full-color OLED display, the Record button, arrow keys, the OK button, and a tube connector to output sounds to the headset consisting of tubes and ear tips.

The proposed devices can detect and display an acoustic based heart rate when presented with consistent heart sounds.

In addition, using a Bluetooth wireless link, the proposed stethoscopes can exchange raw audio data with external devices such as personal computers.

Note: The models DS101 and Omni-Steth are standalone devices and do not require Bluetooth data transfer to fulfill their intended use.

The differences between the proposed stethoscope models DS101 and Omni-Steth are cosmetic: specifically, the design of top housing and keyboard layout. The OLED Display information are identical.

Trade Name	CARDIART Electronic Stethoscope	Omni-Steth Electronic Stethoscope
Model Name	DS101	Omni-Steth
Device Appearance		
Keyboard layout		

V. INTENDED USE AND INDICATIONS FOR USE

Cardiart Electronic Stethoscope (Model DS101)
The Electronic Stethoscope DS101 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.

Omni-Steth Electronic Stethoscope (Model Omni-Steth)
The Electronic Stethoscope Omni-Steth 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 TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technology of the proposed electronics stethoscopes Models DS101 and Omni-Steth are identical to the predicate IMEDIPLUS electronic stethoscope Model DS301 1A in terms of principle of operation, materials, design, user interface, frequency ranges, and auscultation organs. The following include the modifications to the previous design implemented in the proposed stethoscopes:

1. New PCB (Printed Circuit Board) layout
2. New housing with water resistance (IPX4)
3. Rearrangement of the information on OLED display
4. Data transmission via Bluetooth
5. Two AAA 1.2V batteries as power supply
6. Display of Phonocardiogram

Comparison table

Items	Comparison Items	Subject Device		Secondary Predicate Device	Primary Predicate Device	Same/Similar Different /New
		CardiartElectronic Stethoscope (DS101)	Omni-Steth Electronic Stethoscope (Omni-Steth)	3M 3200 (K083903)	DS3011A (K173663)	
1	Regulatory					
	Regulatory No	870.1875	870.1875	870.1875	870.1875	Same
	Classification	Class II	Class II	Class II	Class II	Same
2	Power Source					
	Batteries type	Two AAA battery	Two AAA battery	One AA battery	One NP-120 Lithium battery	Similar with 3M 3200 ; Different from DS3011A
	Battery Life	> 7 Hours	> 7 Hours	50-60 Hours	24 Hours	Different
	Special Adaptors	No	No	No	Yes	Same with 3M 3200 ; Different from DS3011A
3	Features					
	Binaural headset	Yes	Yes	Yes	Yes	Same
	Chest-piece Technology	Single Sided	Single Sided	Single Sided	Single Sided	Same
	Chest-piece Weight	18g	18g	98g	69g	Different
	Clinical Area	Auscultation	Auscultation	Auscultation	Auscultation	Same
	Diaphragm Diameter	4.7cm	4.7cm	5.1cm	4.1cm	Similar with 3M 3200 and

						DS3011A
	Diaphragm Material	Silicone	Silicone	Polyurethane-Coated Silicone	Silicone	Same with DS3011A; Different from 3M 3200
	Ear-tips Type	Soft Sealing	Soft Sealing	Soft Sealing	Soft Sealing	Same
	Headset Material	Brass alloy to electroplate	Brass alloy to electroplate	Wide diameter aerospace alloy / Anodized aluminum	Brass alloy to electroplate	Same with DS3011A
	Length	81 cm	81 cm	69 cm	77 cm	Similar with DS3011A
	Net Weight	214g	213g	185 g	304 g	Different
	Tube Color	Black、Burgundy、Navy Blue	Black、Burgundy、Navy Blue	Black、Burgundy、Navy Blue	Black、Burgundy、Navy Blue	Same
4	Intended Use					
	Intended Use	The CARDIART Electronic Stethoscope 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. 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.	The Omni-Steth Electronic Stethoscope 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. 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.	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 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	Same with DS3011A; similar to 3M 3200. The population is specific to child, adolescents and adults.

					medical diagnostic purposes in clinic or hospital.	
5	Functional					
	Display Screen	OLED 1.46” Full Color	OLED 1.46” Full Color	LCD Monochrome	OLED 1.46” Full Color	Same with DS3011A; similar to 3M 3200.
	Barcode Reader	No	No	No	Yes	Same with 3M 3200
	Three Filter Modes	Yes	Yes	Yes	Yes	Same
	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 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)	Same with DS3011A ; Similar to 3M 3200
	Human Machine Interface	One-hand user interface for auscultation position selection, recording, and function selection.	One-hand user interface for auscultation position selection, recording, and function selection.	Yes	One-hand user interface for patient’s ID scanning, auscultation position selection, recording, and function selection.	Similar with DS3011A
	Recording Number of the sound track	Yes (File name: Year+Month+Hour+Minute+Second)	Yes (File name: Year+Month+Hour+Minute+Second)	Yes (File name: 00x)	Yes (File name: Barcode ID)	Same with 3M3200
	Recording the Organ and Position of the Sound Track	Yes	Yes	No	Yes	Same with DS3011A
6	Software Comparison					
	Heart Rate Detection	Yes	Yes	Yes	Yes	Same
	Heart Rate	Yes	Yes	Yes	Yes	Same

	Display					
	Recording the Sound Track	Yes	Yes	Yes	Yes	Same
	Playback the Sound Track	Yes	Yes	Yes	Yes	Same
	Volume Control	Yes	Yes	Yes	Yes	Same
	Volume Control Scale	Yes 1-10 level	Yes 1-10 level	Yes 0-9	Yes 1-10 level	Same with DS3011A
	Sound Amplification	Yes 24 times	Yes 24 times	Yes 24 times	Yes 24 times	Same
	Filter mode selection	Yes, Bell, Diaphragm, and Wide modes	Yes, Bell, Diaphragm, and Wide modes	Yes Bell, Diaphragm and Extend Modes	Yes, Bell, Diaphragm, and Wide modes	Same with DS3011A
	Automatic turn-off	Yes	Yes	Yes	Yes	Same
	Monitor the battery level	Yes	Yes	Yes	Yes	Same
	Display the Phonogram	Yes, Display the synchronized phonogram on the screen during the auscultation with the CARDIART Electronic Stethoscope	Yes, Display the synchronized phonogram on the screen during the auscultation with the Omni-Steth Electronic Stethoscope	Yes, Display on 3M Littmann® Zargis StethAssist Heart and Lung Sound Visualization Software	Yes, Display the synchronized phonogram on the screen during the auscultation with the IMEDIPLUS Electronic Stethoscope DS3011A	Similar with 3M 3200
	Software of the Connected Device	Yes, IMEDIPLUS DS101-DM software (DS101 Data Management software) (1) Receive and storage the data of sound tracks (2) Display the phonogram of the sound tracks	Yes, IMEDIPLUS DS101-DM software (DS101 Data Management software) (1) Receive and storage the data of sound tracks (2) Display the phonogram of the sound tracks	Yes, 3M Littmann® Zargis StethAssist Heart and Lung Sound Visualization Software	Yes, IMEDIPLUS DS3011A-DM software (DS3011A Data Management software) (1) Receive and storage the data of sound tracks (2) Display the	Similar with3M 3200.

					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.	
7	Function of Data Transfer and the Interface					
	Data Transfer of the Recorded Sound Tracks	Yes, Bluetooth, (transmits the audio data from the stethoscope to the connected device)	Yes, 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 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)	Similar with 3M 3200
	Capable of Storing Data and Latest sound tracks for playback	Save up to 160 10-second sound tracks; Latest 160 sound tracks for playback.	Save up to 160 10-second sound tracks; Latest 160 sound tracks for playback.	Save up to twelve 30-second sound tracks; Latest 12 sound tracks for playback.	Save up to 600 10-second sound tracks; Latest 50 sound tracks for playback.	Similar with 3M 3200 and DS3011A
8	Service and Occupation					
	Warranty Period	1 Years	1 Years	2 Years	2 Years	Different
	Occupatio	Anesthesiologist, Cardiologist,	Anesthesiologist, Cardiologist,	Anesthesiologist,	Anesthesiologist,	Same

	n	Emergency Physician, EMT/EMS, Family Practitioner, Internist, Medical Assistant, Medical Student, Nurse, Nursing Student, Pediatrician, Physician, Respiratory Specialist, Teacher/Professor/Instructor, and Veterinarian.	Emergency Physician, EMT/EMS, Family Practitioner, Internist, Medical Assistant, Medical Student, Nurse, Nursing Student, Pediatrician, Physician, Respiratory Specialist, Teacher/Professor/Instructor, and Veterinarian.	Cardiologist, Emergency Physician, EMT/EMS", Family Practitioner, Internist, Medical Assistant, Medical Student, Nurse, Nursing Student, Pediatrician, Physician, Respiratory Specialist, Teacher/Professor/Instructor, and Veterinarian.	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	User manual	CD-ROM User manual	User manual	Same with DS3011A

VII. PERFORMANCE DATA

Non-Clinical

Risk Analysis
The risk analysis was conducted in accordance with the ISO 14971:2007 standard, which specifies the process for identifying hazards, estimating and evaluating associated risks, controlling the risks, and monitoring the effectiveness of the controls. All the risks of the identified potential hazards caused by the modifications of subject device were identified and evaluated based on severity and occurrence probability. Identified risks were mitigated by implementing risk control measures which were verified to ensure any residual risks were at acceptable levels.

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 (Model DS101/Omni-Steth) complies with the safety standards of ANSI/ AAMI ES 60601-1:2005/(R)2012, the EMC standard of IEC 60601-1-2:2014 and FCC Part 15. The results of radiated emissions, immunity to electrostatic discharges, immunity to radio frequency electromagnetic fields, and power frequency magnetic fields are acceptable.

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

Biocompatibility Evaluation
The biocompatibility was evaluated in accordance with the AAMI ANSI ISO 10993-1:2009 standard and results demonstrate that the proposed devices conform.

Usability Evaluation
The usability evaluation demonstrated that the proposed devices comply with the requirement of Clause 5.3 and 5.7.3 of the international medical device usability engineering standard, IEC 62366:2015. Under conditions of the test specified the usability is acceptable.

The testing took place from June 1 to June 18, 2018, and all participants were screened as appropriate for the intended user of the device. 15 physicians and 15 registered nurses participated in the study conducted in San Diego, California and Saint Louis, Missouri. The conference room, which is the venue of the testing, simulated the clinic or the out-patient clinic and in-hospital setting as in actual use. The lighting level, the fluorescent lamp of white (neutral shades) commonly used in hospitals and clinical room, is about 500 lux. The sound level is under the range 80 dB. In addition, no special training is needed for using the device, all participants consented and were instructed to read the user manual. Hence, the

participants received the user manual before executing the HFE/UE test to learn the process and it was confirmed that all participants had read the user manual. During the test the participants who use our product for the first time, completed all the testing tasks on their own after reading the user manual. They successfully completed the tasks and gave feedback during the interview. The outputs and results did not indicate any use problem and there was no need to perform design modification of user interface or labeling.

The result of the testing shows that the user interface design is simple and easy for user to learn. It is the “Learnability”. There are three modes to be selected for auscultation. Recording the sounds of the three modes within one operation can significantly improves the efficiency of the auscultation and recording of patients’ information. It is the “Efficiency”. All participants were satisfied with the size of the Omni-Steth Electronic Stethoscope and considered the user interface and operation procedures easy to use and memorize, they also praised the function of playing back recordings received from the DS101_DM Software (Data Management) to the device. The participants gave high recognition to the device representing the “Satisfaction”. In addition, Omni-Steth Electronic Stethoscope and the DS101_DM Software (Data Management) achieved the goals of having all participants help demonstrate the safety of the device and no hazards were identified. Overall, the participants indicated the usability of the device is acceptable and therefore the devices are safe and effective.

Wireless Coexistence

The wireless coexistence test results demonstrated that the proposed devices comply with the requirement of ANSI C63.27-2017 - American National Standard for Evaluation of Wireless Coexistence. The result is shown that little interference from Bluetooth and Wi-Fi interfacing over different test distances was noted, and that the heart rate and peak-to-value remained stable.

Splash Water Test

The splash water test results demonstrate the proposed devices comply with IEC / EN 60529:2001 (IPX4 splashing water Test Protected) and the device’s function was normal after testing.

Heart Rate Performance Testing

The comparison bench testing results of heart rate detection function among IMEDIPLUS Electronic Stethoscope DS101, 3M 3200 and IMEDIPLUS Electronic Stethoscope DS3011A provide a detailed analysis of the similarities and differences. The report demonstrates that the heart rate detection of IMEDIPLUS Electronic Stethoscope DS101 is substantially equivalent to 3M 3200 (Secondary Predicate Device) and DS3011A (Primary Predicate Device) within the heart rate range of 30-180 bpm.

Audio Performance Testing

The comparison bench testing results of audio performance among DS101, DS101_DM Software (Data Management), 3M 3200 and DS3011A provide a detailed analysis of the similarities and differences. The report demonstrates that the audio performance of IMEDIPLUS Electronic Stethoscope DS101 and DS101_DM Software (Data Management) are substantially equivalent to the Secondary Predicate device

3M 3200 while audio frequency is below 1 kHz. In addition, the IMEDIPLUS Electronic Stethoscope DS101 and DS101_DM Software (Data Management) are substantially equivalent to the predicate device IMEDIPLUS Electronic Stethoscope DS3011A for bell, diaphragm and wide frequency band mode.

Clinical

There is no difference in the intended use, operating principle, and fundamental technology, in comparison to the predicate device, thus clinical testing was deemed unnecessary. Exchange of audio data with external devices is accomplished in the predicate device with a Micro SD card and via a Bluetooth wireless link in the proposed devices.

VII. CONCLUSIONS AND SUMMARY

The proposed electronic stethoscopes models DS101 and Omni-Steth have the same intended use and fundamental scientific technology as the predicate model DS3011A, which received 510(k) clearance K173663. Modifications incorporated in the subject device include new PCB layout, new housing with water resistance (IPX4), rearrangement of the information on OLED display, data transmission via Bluetooth, two AAA 1.2V batteries as power supply and phonocardiogram display. Results of risk analysis and performance data demonstrate that the design outputs of the modified device meet the design requirements and residual risk levels are acceptable. In summary, the proposed electronic stethoscopes described in this submission are substantially equivalent to the predicate device without raising any new issues of safety or effectiveness.