EPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 30, 2016

Imediplus Inc.
Shirley Lai
Regulatory Specialist
2F, 12, ShengYi Rd. Sec. 2
Zhubei City, Hsinchu County, 30261 TW

Re: K160023
Trade/Device Name: Electronic Stethoscope DS301
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: August 23, 2016
Received: August 26, 2016

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. 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.

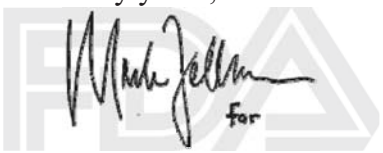
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160023

Device Name
Electronic Stethoscope DS301.

Indications for Use *(Describe)*
The IMEDIPLUS Electronic Stethoscope DS301 is intended for the detection, amplification and recording of sounds from the heart, lung, 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.

510(k) Submission
Electronic Stethoscope DS301

Section 5

510(k) Summary

510(k) Summary

The Assigned 510(k) Number: K160023
Date Prepared: Dec.18. 2015.

The Assigned 510(k) Number: K160023/S001
Deficiencies Formal Reply Date: August 27. 2016.

I. SUBMITTER INFORMATION:

Submitter:
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Date Prepared: September 22, 2016.

II. PREDICATE DEVICE

Predicate Device:

3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200

Predicate Device Identification Table 1.

Subject Device	Predicate Device	Manufacturer	510(k) Number
IMEDIPLUS Electronic Stethoscope DS301	3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200	3M COMPANY	K083903

III. DEVICE

Common Name and Classification Table 2.

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

IV. DEVICE DESCRIPTION

The IMEDIPLUS Electronic Stethoscope DS301 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. After detection and amplification, the sounds are transferred to the user's ears via an active speaker and passive sound tubes. It could also identify the recording number by 1-D barcode reader, indicate the sound location by intuitive keypad, and simultaneously record the sounds from different sites.

The one-hand user interface includes a full-color OLED display and 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. Sound processing is operated with the aid of a digital signal processor.

The IMEDIPLUS Electronic Stethoscope DS301 could also exchange audio data with an external personal computing device using micro SD card. Every single audio file stored in micro SD card was labeled with the user's ID, recording number and indicated position. And the recorded audio data only can be replayed by IMEDIPLUS Electronic Stethoscope DS301, but cannot be replayed by personal computing device.

The IMEDIPLUS Electronic Stethoscope DS301 does not incorporate any off-the-shelf (OTS) software.

The IMEDIPLUS Electronic Stethoscope DS301 operates on one 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 include adaptor and charger.
- Micro SD card for exchange audio data.

V. INDICATION FOR USE

The IMEDIPLUS Electronic Stethoscope DS301 is intended for the detection, amplification and recording of sounds from the heart, lung, 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. COMPARISION OF TECHNOLOGY CHARACTERISTICS WITH THE PREDICATE DEVICE

The IMEDIPLUS Electronic Stethoscope DS301 and 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200 are based on the following same technological elements:

- Binaural headset – used to send the sounds to user's ear.
- Chest-piece – used to pick up sounds from patient's internal organ.
- Sound amplifier – used to amplify the sounds from chest-piece.
- Battery – used to power the device.
- Digital signal processor – used for sound processing.
- Display – used to show the operation information.
- Keypad – used to control and setup the device.
- Detect and display heart rate – used to monitor patient's heart rate.
- Record and playback – used to record and playback a sound track.
- Select filter – used to better emphasize the specific patient sounds of interest.
- Adjust sound amplification level – used to control the sound level.
- Monitor Battery Life – used to indicate the battery life.

The following differences exist between the IMEDIPLUS Electronic Stethoscope DS301 and the predicate device (3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200):

- 1D Barcode reader – used to identify the user's ID and recording number.
- Micro SD card – used for sounds track exchange.
- Organ position indication – used to indicate the auscultated organ.
- Auscultation position indication – used to indicate the auscultation position of organ.
- Intuitive keypad – used to choose the organ position between heart and lung during auscultation.
- A/P CHEST Key – used to change the organ position between "Anterior Chest" and "Posterior Chest".

Table 3 summarizes the technology characteristics between the IMEDIPLUS Electronic Stethoscope DS301 and predicate device.

Table 3. Specification comparison table

Features	**Candidate Device** IMEDIPLUS Electronic Stethoscope DS301	**Predicate Device** 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200	Same/Similar Different /New
Regulatory			
Regulatory No	870.1875	870.1875	Same
Classification	Class II	Class II	Same
Power Source			
Source type	Battery	Battery	Same
Battery type	One Rechargeable NP-120 lithium battery	One AA battery	Difference
Battery operation time	24 Hours	50-60 Hours	Difference
Intended use			
Intended use	The IMEDIPLUS Electronic Stethoscope DS301 is intended for the detection, amplification and recording of sounds from the heart, lung, 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	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.	Similar The population is specific to child, adolescent and adult.

Features	**Candidate Device** IMEDIPLUS Electronic Stethoscope DS301	**Predicate Device** 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200	Same/Similar Different /New
	patients. It is used for any subject undergoing a physical examination and intended only for medical diagnostic purposes in clinic or hospital.	It can be used on any person undergoing a physical assessment.	
Functional			
Binaural headset	Yes	Yes	Same
Chest-piece	Yes	Yes	Same
Sound processing	Digital signal processor	Digital signal processor	Same
Display function	Yes,	Yes,	Same
Display type	1.46” Full Color OLED	LCD	Difference OLED has wide view angle, high responsive time, high brightness, low power consumption and full color characteristics .
Select filter	Bell (20-200 Hz) Diaphragm (100-500 Hz)	Bell (20-200 Hz) Diaphragm (100-500 Hz)	Same

Features	**Candidate Device** IMEDIPLUS Electronic Stethoscope DS301	**Predicate Device** 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200	Same/Similar Different /New
	Wide (20-1000Hz)	Extend range (50-500 Hz)	Difference, See the bench test report of audio.
Detect and display heart rate function	Yes,	Yes,	Same
Detect and display heart rate range	30-180 bpm	30-199 bpm	Difference
Record and playback function	Yes	Yes	Same
Number of record and playback sounds	Save up to 999 10-second sound tracks; Latest 15 sound tracks for playback.	Save up to twelve 30-second sound tracks; Latest 12 sound tracks for playback.	Difference
Sound Amplifier	Yes, Up to 24X	Yes, Up to 24X	Same
Volume control	Yes	Yes	Same
Volume control level	1-10 level	1-9 level	Difference
Automatic power off	Yes	Yes	Same
Monitor battery life function	Yes	Yes	Same
Monitor battery life degrees	5 degrees	4 degrees	Difference

Features	**Candidate Device** IMEDIPLUS Electronic Stethoscope DS301	**Predicate Device** 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200	Same/Similar Different /New
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”.	Same
Sound track transfer function	Yes	Yes	Same
Sound track transfer interface	Micro SD card	Bluetooth	Different
Barcode Reader	Yes, 1D Barcode reader	No	New
Organ position indication	Yes, To indicate the auscultation organ.	No	New

Features	**Candidate Device** IMEDIPLUS Electronic Stethoscope DS301	**Predicate Device** 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200	Same/Similar Different /New
Auscultation position indication	Yes, To indicate the auscultation position of organ.	No	New
Intuitive keypad	Yes, To choose the organ position between heart and lung during auscultation.	No	New
A/P CHEST key	Yes, To change the organ position between “Anterior Chest” and “Posterior Chest”.	No	New

VII. PERFORMANCE DATA

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

Biocompatibility

The duration of skin contact to the patient is generally less than 5 minutes and the duration of skin contact to the doctor is generally less than 3 hours. Because the duration is short and all the materials of contact parts are used in common medical device industry for years, the biological hazards are assessed as low risk based on FDA #G95-1 and ISO10993-1. It is assessed not 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 DS301 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 and IEC 61000-4-11.

Software Verification and Validation Testing

The provided software verification and validation comply with the requirements of IEC 62304:2006, AAMI TIR45:2012 and IEC/TR80002-1:2009. The software for this device is considered as a “moderate” level of concern, 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 Integrated Service Technology, Inc. The reliability report shows the conditions of operation, storage and transportation environment for the IMEDIPLUS Electronic Stethoscope DS301. 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 DS301 complies with the IEC 62471: 2006 (First Edition) and EN 62471:2008 standards.

Usability Evaluation

The usability evaluation complies with the requirement of Clause 5.3.2 and 5.8 of the international medical device usability engineering standard, IEC 62366:2007 and IEC 60601-1-6.

Performance Testing-Bench

The comparison report of heart rate calculation between IMEDIPLUS Electronic Stethoscope DS301 and 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200 provide a detailed analysis of the similarities and differences. The reports demonstrate that the heart rate detection function of IMEDIPLUS Electronic Stethoscope DS301 are substantially equivalent to the predicate device 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200 with the conditions of heart rate in 30-180 bpm

The comparison report of audio performance between IMEDIPLUS Electronic Stethoscope DS301 and 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200 provide a detailed analysis of the similarities and differences. The reports demonstrate that the audio performance of IMEDIPLUS Electronic Stethoscope DS301 are substantially equivalent to the predicate device 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200 with the conditions of audio frequency below 1 kHz.

Clinical Evaluation

The clinical evaluation is performed by 4 testers, who are clinically certified and qualified professionals. Three subject groups (3 children, 3 adolescents and 3 adults) are defined to conduct the clinical evaluation. The statistical analysis of the

questionnaire show that the medical equipment (IMEDIPLUS Electronic Stethoscope DS301) can meet the basic principles of safety and effectiveness when used in Child, Adolescent and Adult for auscultation of heart, chest, bowel and neck.

List of Standards

The IMEDIPLUS Electronic Stethoscope DS301 conforms to the following standards:

[1] ISO14971, *Medical devices-application of risk management to medical devices*, 2007-03-01.

[2] AAMI ANSI IEC 62304, *Medical device software -- Software life cycle processes*, 2006-05-01.

[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] IEC 62366-1, *Medical devices -- Part 1: Application of usability engineering to medical devices,* 2015-02-01.

[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,* 2012-07-01.

[8] IEC 60601-1-6, *Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability,* 2010-01-27.

[9] 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

[10] 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.

[11] IEC 62471, *Photobiological Safety Of Lamps And Lamp Systems*, 2006-07-26.

Performance Data Summary

The IMEDIPLUS Electronic Stethoscope DS301 has similar safety and effectiveness profiles with the predicate device, 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200.

VIII. CONCLUSIONS

The information provided in this 510(k) submission shows that the IMEDIPLUS Electronic Stethoscope DS301 is substantially equivalent to the predicate device, 3M™ LITTMANN® ELECTRONIC STETHOSCOPE MODEL 3200, cleared under K083903. The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the IMEDIPLUS Electronic Stethoscope DS301 device should perform as intended in the specified use conditions. The clinical evaluation data demonstrate that the IMEDIPLUS Electronic Stethoscope DS301 device performs comparably to the predicate device. The IMEDIPLUS Electronic Stethoscope DS301 is able to achieve the same safety and effectiveness as the predicate device.