July 10, 2020

HD Medical, Inc.
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services LLC
1000 Westgate Drive, Suite 510k
Saint Paul, Minnesota 55114

Re: K201299
Trade/Device Name: HD Steth
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD, DQC, DPS
Dated: May 14, 2020
Received: May 15, 2020

Dear Prithul Bom:

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,

LT 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)*
K201299

Device Name
HD Steth

Indications for Use *(Describe)*
HD Steth is an electronic stethoscope meant to assist a qualified clinician to capture, record and replay heart sounds and electrocardiogram (ECG or EKG) rhythm. It is intended to be used on one patient at a time. Heart sounds (PCG) and 1-lead EKG rhythm are acquired and displayed simultaneously on an accompanying mobile application on a hand-held smart device like a phone or tablet. The waveforms can be recorded and saved on the smart device on which the app is running.

The device has 3 auscultation modes – Bell, Diaphragm and Lung (Wide). These modes and volume levels can be changed by the press of a button. The EKG rhythm recording assists in getting an indicative Heart Rate (HR) that gets displayed on a display panel on the device.

The device must be used in a clinical setting by trained and qualified personnel only. HD Steth is not intended to be used as a diagnostic device. It does not supersede the judgement of a qualified clinician. The device is intended to aid the physician in the evaluation of PCG and EKG rhythm. The clinicians are completely responsible for reviewing and interpreting the results, along with all other relevant information, when making a referral decision.

Caution: The sale of this device is restricted to licensed clinicians or entities referred to by a licensed clinician. It is intended for use by a licensed clinician 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 – HD Steth

I. SUBMITTER

HD Medical Inc.
3561 Homestead Road, Suite #146, Santa Clara, CA 95051
USA Telephone: +1 408-338-6244
Contact Person: Venkat Raman
Date Prepared: June 23, 2020

II. DEVICE

Name of Device : HD Steth
Common Name : Electronic Stethoscope
Classification Name : Electronic Stethoscope, Phonocardiograph, Cardiac monitor (including cardiotachometer and rate alarm).
Regulation Number : 21 CFR §870.1875, 21 CFR §870.2390, 21 CFR §870.2340
Product Classification Code : DQD, DQC, DPS
Regulatory Class : Class II

III. PREDICATE/ REFERENCE DEVICE

PREDICATE DEVICE
Predicate Trade Name : Cardiosleeve, 510(k) K131287
Manufacturer : Rijuven
Classification Name : Electronic Stethoscope, Phonocardiograph
Regulation Number : 21 CFR §870.1875, 21 CFR §870.2390
Product Classification Code : DQD, DQC
Regulatory Class : Class II

REFERENCE DEVICE
Reference Trade Name : ViScope, 510(k) K100531
Manufacturer : HD Medical

IV. DEVICE DESCRIPTION

HD Steth is an electronic audio-visual stethoscope with integrated electrodes for electrocardiogram (ECG or EKG) rhythm. HD Steth is designed to acquire heart sounds through a diaphragm and 1-lead EKG rhythm through three fixed electrodes integrated around the diaphragm. The device has 3 auscultation modes – Bell, Diaphragm and Lung (Wide). The EKG rhythm recording assists in getting an indicative Heart Rate (HR) that gets displayed on a display panel on the device. Both the heart sounds or phonocardiogram (PCG) and the EKG rhythm are acquired simultaneously and can be visualized, recorded and replayed using an

accompanying mobile application. HD Steth provides high fidelity audio in addition to visually observing a PCG and ECG Rhythm signal.

Device Accessories:

1. Diaphragm (HDS060-001)
   Use only HD diaphragm with the device. Use of non-HD diaphragms can result in faulty audio and display and possible analysis irregularities in any future detection/screening algorithms.

2. USB Cable (HDS060-002)
   Micro USB Type-B Male connector to USB 4-Pin Type-A Male connector can be used to connect the device to the charger. Length is 1 meter.

3. Earplugs (HDS060-003)
   Use only HD earplugs.
   Use of non-HD earplugs can result in pain in ears due to material hardness and may degrade audio.

4. Battery (HDS060-004)
   Rechargeable Li-Ion 18650 (Size) 3400mAh 3.7 V– 1 No.

5. Battery Charger (HDS060-005)
   Input: 100-240V AC, 50/60 Hz,
   Output: 5.0V DC, 2000 mA

6. HD Speaker (HDS060-006)
   HD Speaker is used to replaying recorded audio.

V. INDICATIONS FOR USE

HD Steth is an electronic stethoscope meant to assist a qualified clinician to capture, record and replay heart sounds and electrocardiogram (ECG or EKG) rhythm. It is intended to be used on one patient at a time. Heart sounds (PCG) and 1-lead EKG rhythm are acquired and displayed simultaneously on an accompanying mobile application on a hand-held smart device like a phone or tablet. The waveforms can be recorded and saved on the smart device on which the app is running.

The device has 3 auscultation modes – Bell, Diaphragm and Lung (Wide). These modes and volume levels can be changed by the press of a button. The EKG rhythm recording assists in getting an indicative Heart Rate (HR) that gets displayed on a display panel on the device.

The device must be used in a clinical setting by trained and qualified personnel only. HD Steth is not intended to be used as a diagnostic device. It does not supersede the judgement of a qualified clinician.

The device is intended to aid the physician in the evaluation of PCG and EKG rhythm. The clinicians are completely responsible for reviewing and interpreting the results, along with all other relevant information, when making a referral decision.

VI. COMPARISON TO THE PREDICATE DEVICE

Both the HD Steth and the predicate device, Cardiosleeve (K131287) are both Class II, electronic stethoscopes intended for audio and visual display of heart sounds and electrocardiogram (ECG) rhythm using dry-electrodes, on a single patient at a time. The Cardiosleeve and HD Steth provide visual display of the phonocardiogram and 1-Lead EKG rhythm on a mobile application through Bluetooth connectivity for visualization. HD Steth and Cardiosleeve both use rechargeable batteries to power the devices.

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

Table 1: Comparison of HD Steth with Primary Predicate Device Cardiosleeve (K131287).

	HD Steth	Predicate Device: Cardiosleeve (K131287)	Comments
Classification Comparison			
Regulation Name	Electronic Stethoscope	Electronic Stethoscope	Same
Regulation Number	21 CFR870.1875 21 CFR 870.2390 21 CFR 870.2340	21 CFR870.1875 21 CFR870.2390	Same
Regulatory Class	Class II	Class II	Same
Product Code	DQD, DQC, DPS	DQD, DQC	Same
Indication for Use Comparison			
Indications for Use	HD Steth is an electronic stethoscope meant to assist a qualified clinician to capture, record and replay heart sounds and electrocardiogram (ECG or EKG) rhythm. It is intended to be used on one patient at a time. Heart sounds (PCG) and 1-lead EKG rhythm are acquired and displayed simultaneously on an accompanying	The CardioSleeve System consisting of the CardioSleeve Front-End stethoscope and ECG device, mobile heart sound recording application and the remote diagnostic heart murmur software is a decision support device intended to be used on a	Substantially Equivalent

	mobile application on a hand-held smart device like a phone or tablet. The waveforms can be recorded and saved on the smart device on which the app is running. The device has 3 auscultation modes – Bell, Diaphragm and Lung (Wide). These modes and volume levels can be changed by the press of a button. The EKG rhythm recording assists in getting an indicative Heart Rate (HR) that gets displayed on a display panel on the device. The device must be used in a clinical setting by trained and qualified personnel only. HD Steth is not intended to be used as a diagnostic device. It does not supersede the judgement of a qualified clinician. The device is intended to aid the physician in the evaluation of PCG and EKG rhythm. The clinicians are completely responsible for reviewing and interpreting the results, along with all other relevant information, when making a referral decision. Caution: The sale of this device is restricted to licensed clinicians or entities referred to by a licensed clinician. It is intended for use by a licensed clinician only.	single patient to assist the medical examiner in analyzing cardiac sounds for the identification and classification of suspected murmurs. It is used to distinguish between normal / physiological and pathological heart murmurs by recording the acoustic signal of the heart and the ECG signal simultaneously and analyze these signals. The acoustic heart signal is analyzed to identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected murmurs. CardioSleeve indicates whether or not a recorded heart sound contains a suspected heart murmur. The device must be used in a clinical setting by trained personnel with the prescribed accessories and all relevant patient information must be taken into consideration before a diagnosis is made. The interpretations of heart sounds offered by the CardioSleeve device are only significant when used in conjunction with physician over-read as	

		well as consideration of all other relevant patient data. CardioSleeve is not intended to be a diagnostic device. It does not supersede the judgment of the qualified medical personnel. The device is intended to aid the physician in the evaluation of heart sounds. The physicians are responsible for reviewing and interpreting the results, along with the auscultation findings and medical history, when making a referral decision. Caution: This device is intended for sale to and use by a licensed clinician only.	
Technological Characteristics Comparison			
EKG Rhythm Capabilities	Yes (3 Electrodes) 1-Lead	Yes (3 Electrodes) 1-Lead	HD Steth and Cardiosleeve have the capability to acquire 1-Lead EKG rhythm and Cardiosleeve, the HD **Steth** also provides an EKG Rhythm by using three dry electrodes.

Phonocardiogram and visualization of sounds	Yes On accompanying App	Yes On accompanying App	The Cardiosleeve and HD Steth provides visual display of the phonocardiogram and 1-Lead EKG rhythm on a mobile application through Bluetooth connectivity.
Signal transmissions to Mobile Application via Bluetooth	Yes – uses Bluetooth Compatible with Android devices	Yes – uses Bluetooth Compatible with iOS and Android devices	The Cardiosleeve and HD Steth use Bluetooth technology to connect their respective Mobile Application for Visualization
Operating Indications	Operating Mode Battery Charge Level, Record Indication, Bluetooth Connectivity, Audio modes	LED on Device for Battery ChargeLevel, Record Indication, Bluetooth Connectivity	HD Steth and Cardiosleeve have display indications for the features/ modes of the device.
Power Source	One Li-ion battery 3400mAh, 3.7V	One 3.7 V Lithium Ion Rechargeable Batteries	HD Steth and Cardiosleeve both use Rechargeable Batteries to power the devices

VII. PERFORMANCE DATA

Performance testing was conducted to support the design and development of the proposed device including biocompatibility testing, electrical safety and electromagnetic compatibility (EMC) testing, and the verification and validation testing: Mobile Application Software, Hardware System Testing, Firmware System Testing and ECG (EKG) and PCG Simulation Testing.

Report Document Number	Test Description	Referenced Standard	Test Result
Electromagnetic Compatibility Test (VOL_036_ EMC)			
VOL 036 001_19646664 001 - Test report - EMI-EMC	EMI/EMC test report	ANSI /AAMI /IEC 60601-1-2:2014 / EN 60601-1-2:2015	Pass
	Harmonics on AC Mains		Pass
	Voltage Fluctuation on AC Mains		Pass
	Mains Terminal Continuous Disturbance Voltage (Conducted Emission)		Pass
	Radiated Emission		Pass
	Radiated Radio-Frequency Electromagnetic Fields (Radiated Susceptibility)		Pass
	Proximity Fields From RF Wireless Communications Equipment		Pass
	Conducted Disturbances Induced by Radio-Frequency Fields (Conducted Susceptibility)		Pass
	Power Frequency Magnetic Fields		Pass
	Electrical Fast Transients and Bursts		Pass
	Surges		Pass

	Electrostatic Discharges		Pass
	Voltage Dips		Pass
	Voltage Interruptions		Pass

Bluetooth (BT) Coexistence Test (VOL_037_Coexistence testing)			
VOL 037 001_Report-HDMG0002 Combined	Wireless Coexistence	ANSI C63.27:2017 (Method ANSI C63.27:2017 EN 300 328 V2.1.1:2016)	Pass
	Unintended Signal Baseline		Pass
	waveform of the test signal		Pass
	FCC15.247:2020 Bluetooth(FHSS)	ANSI C63.10:2013 KDB 558074	Pass
	Output Power		Pass
	Spurious Radiated Emissions		Pass
	Antenna Heights		Pass
	BLE power		Pass
	Low 2.716 dBM		Pass
	Medium 2.896 dBM		Pass
	High 1.723 dBM		Pass

Additional verification and validation testing also demonstrated successful assessment of Mobile Application Software, Hardware System, Firmware System and ECG (EKG) and PCG Simulation.

The collective performance testing demonstrates that HD Steth does not raise any different questions or effectiveness when compared to the predicate device. The results of performance testing demonstrate that the HD Steth performed as intended.

VIII. CONCLUSIONS

The indications for use, technological characteristics and performance testing support that the proposed device is substantially equivalent, and as safe and effective as the predicate device, and raises no new issues of safety or effectiveness.