July 27, 2021

GV Concepts
Faye Liu
Official Correspondent
3034 Bradshaw Dr
San Jose, California 95148

Re: K210736
Trade/Device Name: doctorgram Stethoscope DES-I
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: June 26, 2021
Received: June 29, 2021

Dear Faye Liu:

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,

LCDR 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K210736

Device Name

doctorgram™ Stethoscope DES-I

Indications for Use *(Describe)*

The doctorgram™ Stethoscope DES-I is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. The doctorgram™ Stethoscope DES-I is intended for use on pediatric and adult patients. The doctorgram™ Stethoscope DES-I is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis.

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.

1. General Information

510(k) Sponsor:	GV Concepts Inc
Address:	3240 S. White Road, #286, San Jose, CA 95148
Applicant Contact Person:	Ching-Kay Chow Phone: (408) 781-3861 Email: chingkay.chow@gvconcepts.com
Correspondence person:	Faye Liu, Ph.D., RAC Phone: (408) 714-0188 Email: faylee2009@gmail.com

2. Device Identification

Proposed Device:

Proprietary Name:	doctorgram™ Stethoscope DES-I
Classification Name:	Electronic Stethoscope
Regulation Number:	870.1875
Product Code:	DQD
Regulatory Class:	II

Predicate Device:

Proprietary Name:	Eko CORE Electronic Stethoscope System
Premarket Notification	K200776
Classification Name:	Electronic Stethoscope
Regulation Number:	870.1875
Product Code:	DQD
Regulatory Class:	II

3. Device Description

The doctorgram™ Stethoscope DES-I (hereafter referred to as DES-I stethoscope) is a digital stethoscope device designed for use by health care professionals as well as lay users in clinical or non-clinical environments. It can electronically amplify, filter and transfer sounds to the accompanying mobile application for storage and sharing or can transmit the data for telemedicine use. It also enables regular users to listen to their body sounds (lungs, heart, arteries, veins, Gastrointestinal tract, etc.) and record and share it with their physicians.

It consists of two primary components: 1) The DES-I stethoscope handheld piece, a stand-alone electronic stethoscope and 2) Doctor's Ear, a mobile application that pairs with the Doctorgram Stethoscope.

- The DES-I stethoscope handheld piece is used to convert sound to electronic form, for monitoring directly using headphones/earbuds and/or transmitting the audio data to a mobile device via Bluetooth®. It includes a power button, volume adjustment buttons, Bluetooth® button and LED light indicators.

- The mobile application captures audio data from the handheld piece and provides data visualization, secure data storage, audio playback, and sharing features. The Doctor's Ear application can be directly downloaded from Apple App Store.

These features enable a healthcare professional to monitor patients, seek out second opinions from a specialist or use the device for telemedicine use.

4. Intended Use/Indications for Use

The doctorgram™ Stethoscope DES-I is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. The doctorgram™ Stethoscope DES-I is intended for use on pediatric and adult patients. The doctorgram™ Stethoscope DES-I is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis.

5. Technological Comparison

The DES-I stethoscope has similar overall operational and technological characteristics as compared to the predicate device. The predicate device has the ability to attach to a standard analog stethoscope; the DES-I stethoscope is a stand-alone electronic stethoscope with a built-in analog stethoscope head. Both devices include both digital and analog auscultation modes. Both devices connect via Bluetooth to the accompanying mobile App for visualization, recording and transfer of data. Both devices included on/off power buttons and volume adjustment controls. Both devices have the same frequency range and have similar maximum sound level.

A table comparing the key features of the subject and predicate devices is provided in **Table 5-1, Substantial Equivalence Discussion.**

Table 5-1, Substantial Equivalence Discussion

Elements of comparison	doctorgram Stethoscope DES-I (Candidate Device)	Eko Electronic Stethoscope System (OTC) (Predicate device), K200776	Comparison
Regulatory Data			
Regulatory Class	Class II	Class II	Identical
Classification name	Electronic Stethoscope	Electronic Stethoscope	Identical
Regulation Number	21 CFR 870.1875	21 CFR 870.1875	Identical
Product code	DQD; Electronic stethoscope	DQD; Electronic stethoscope	Identical
Manufacturer	GV Concepts, Inc.	Eko Devices, Inc.	NA
Indications for Use			
Indications for use	The doctorgram™ Stethoscope DES-I is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. The doctorgram™ Stethoscope DES-I is intended for use on pediatric and adult patients. The doctorgram™ Stethoscope DES-I is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis.	The Eko CORE is an electronic stethoscope that enables amplification, filtering, and transmission of auscultation sound data (heart, lungs, bowel, arteries, and veins), whereby a clinician at one location on network can listen to the auscultation sounds of a patient on site or at a different location on the network. Eko CORE is intended for use on pediatric and adult patients. The Eko CORE is intended to be used by professional users in a clinical environment or by lay users in a nonclinical environment. The device is not intended for self-diagnosis.	Identical

Characteristics			
Principles of operation	The device consists of a handheld piece with built-in stethoscope head. Acoustic sound can be sent analoglly to the headphone or digitally via Bluetooth to compatible mobile phones or tablets. 1. Dispositive introduced in an acoustic stethoscope and gives sound amplification and audio transmission to a smartphone via Bluetooth that allows the user to open and playback sounds in a mobile application on compatible iOS smartphones and tablets. 2. Use it as standalone stethoscope by connecting earbud headphone via 3.5mm jack	Dispositive introduced in an acoustic stethoscope and gives sound amplification and audio transmission to a smartphone via Bluetooth that allows the user to open and playback sounds in a mobile application on compatible iOS smartphones and tablets.	Similar with minor differences
Clinical conditions	Human body sounds related	Human body sounds related	Identical
Clinical Use	Electronic stethoscope	Electronic stethoscope	Identical
Stethoscope Type	Built-in stethoscope head	Attachment to an analog stethoscope; compatible stethoscopes include: -Littmann 3M Cardiology II/III -WelchAllyn Harvey Elite -ADC601 lines of analog stethoscopes	Similar with minor differences
Prescription/OTC	OTC use	OTC use	Identical
User Interface	On/Off Power button Volume adjustment LED status indicator; Mobile App	On/Off Power button Volume adjustment LED status indicator; Mobile App	Identical

Technical equivalence			
Analog/ Digital Interoperability	Yes	Yes	Identical
Sound Amplification	Yes	Yes	Identical
Volume Control	Yes	Yes	Identical
Record and Playback Sounds	Yes	Yes	Identical
Data Transfer to Compatible Computing platform	Yes	Yes	identical
Connectivity	Bluetooth®	Bluetooth®	Identical
Energy Source	Litium Ion Battery	Lithium Ion Battery	Identical
System required	iOS	Android and iOS	Similar with minor differences
Hardware and software platforms	Mobile and tablets (no computer software yet)	Mobile devices or tablets	Identical
Connections	Micro USB connector only for charging internal battery of the device	Micro USB connector only to charge internal battery of the device	Identical
Frequency range	20 Hz to 2KHz	20 Hz to 2 kHz	Identical
Signal Input Method	Sound waves collected via a Transducer Electro Microphone	Sound waves collected via a Transducer Electro micro-phone	Identical
Audio Output Method	3.5mm earbud headphone	Speakerphone	Similar with minor differences

Software Function	(1) Receive and store the data of sound tracks (2) Display the phonogram of the sound tracks (3) Replay the audio data in the connected device installed with software; share the audio file with physicians.	(1) Receive and store the data of sound tracks (2) Display the phonogram of the sound tracks (3) Replay the audio data in the connected device installed with software; share the audio file with physicians.	Identical
Performance requirements	The operating range is - 10ºC to 40ºC, and 0% to 90% relative humidity	The operating range is - 10ºC to 40ºC, and 0% to 90% relative humidity	Identical
Electrical Safety Standards Met	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	Identical
Biological Equivalence			
Materials	Body: ABS	Body: ABS (Acrylonitrile Butadiene Styrene).	Identical
Contact with human tissues or body fluids	Attached stethoscope head comes in direct contact with patient's skin; the body doesn't contact patient's body.	The body does not contact patient´s body. Attached stethoscope does.	Similar with minor differences
Sterility	Not intended to be sterilized	Not intended to be sterilized	Identical

6. Performance Testing

The DES-I stethoscope has undergone extensive bench verification, as well as software verification and validation. Electrical safety and EMC were successfully conducted, and Bluetooth SIG Qualification were obtained. The OTC use of the device was assessed in usability testing with passing results.

In all instances, the device functioned as intended. Based on the testing results, the device has a safety and effectiveness profile that is similar to the predicate device.

7. Conclusion

The DES-I stethoscope has the same intended use and indications, technological characteristics, and principles of operation as its predicate device.

The minor differences in product design do not raise different questions of safety and effectiveness when used as labeled. Performance data demonstrate that the DES-I stethoscope is as safe and effective as the predicate device.