January 10, 2020

iMedrix Inc. (formerly Piitech Inc.)
Srikanth Jadcherla
Chief Executive Officer
1525 McCarthy Blvd., Suite 1059
Milpitas, California 95035

Re: K191692
Trade/Device Name: KardioScreen
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: December 11, 2019
Received: December 12, 2019

Dear Srikanth Jadcherla:

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,

Jennifer Shih
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)*
K191692

Device Name
KardioScreen

Indications for Use *(Describe)*
KardioScreen is a portable and mobile device intended to acquire a resting, diagnostic ECG using surface electrodes from adult patients and pediatric patients age 14-21 years. The device is intended to be used by doctors and/or trained healthcare professionals in a hospital, medical professional's facility, clinic, physician's office or any medical outreach center. The device can acquire, display, analyze and print either 6-lead or 12-lead electrocardiograms which can be exported for external use. The recorded ECG signals can help users to analyze and diagnose heart disease, but the device is not meant as a sole means of 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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I. SUBMITTER

iMedrix Inc. (formerly Piitech Inc.)
1525 McCarthy Blvd., Suite 1059
Milpitas, CA 95035

Phone: 866-463-3749
Fax: 866-463-3749

Contact Person: Srikanth Jadcherla, Chief Executive Officer

Date Summary Prepared: December 11, 2019

II. DEVICE

Proprietary Name: KardioScreen

Classification Name: Electrocardiograph

Product Code: DPS

Regulation: 21 CFR 870.2340

Regulatory Class: II

III. PREDICATE DEVICE

The primary predicate device is Edan Instruments, Inc.'s PADECG, which was cleared under K161302.

This predicate device has not been to subject of a recall.

IV. DEVICE DESCRIPTION

KardioScreen is a portable battery-operated electrocardiograph designed to acquire either a 6-lead or 12-lead resting, diagnostic electrocardiogram (ECG) using surface electrodes from adult patients and pediatric patients aged 14-21 years. The device consists of the following three (3) parts:

1. Electrodes and patient cable with KardioScreen Converter
2. KardioScreen device
3. KardioScreen application running on Android tablet

The device is supplied with patient cables with lead wires that connect to any commercially available disposable ECG electrode. Optional reusable clamp electrodes can be used for the limb leads and bulb electrodes for the chest leads.

Once the electrodes have been connected to the patient, the ECG cable with KardioScreen Converter is then connected to the "ECG" port on the KardioScreen device. This module receives the electrical ECG signals, performs processing on the signals and then wirelessly transmits the ECG data through a Bluetooth Low Energy (BLE) interface to a mobile application running on an Android tablet. The ECG waveforms are displayed on the KardioScreen application for viewing and analysis. From the Android tablet, the ECG report can be printed or exported for external use.

V. INTENDED USE / INDICATIONS FOR USE

KardioScreen is a portable and mobile device intended to acquire a resting, diagnostic ECG using surface electrodes from adult patients and pediatric patients age 14-21 years. The device is intended to be used by doctors and/or trained healthcare professionals in a hospital, medical professional's facility, clinic, physician's office or any medical outreach center. The device can acquire, display, analyze and print either 6-lead or 12-lead electrocardiograms which can be exported for external use. The recorded ECG signals can help users to analyze and diagnose heart disease, but the device is not meant as a sole means of diagnosis.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

iMedrix's KardioScreen and Edan Instruments, Inc.'s PADECG have the same intended use, same clinical setting, same target user, same ECG measurements, and same pace detection. Both devices comply with the electrical safety, EMC and electrocardiograph safety and performance standards and are defibrillation-proof.

Both devices transmit wirelessly to a mobile device, though KardioScreen is designed to work with Android tablets while PADECG works with iOS devices. KardioScreen can also capture a 6-lead ECG, in addition to the standard 12-lead ECG that PADECG captures. Both devices are designed for adult and pediatric populations, though KardioScreen restricts pediatric use to ages 14 and older.

These differences in technological characteristics do not raise new issues of safety or effectiveness.

VII. PERFORMANCE DATA – NON-CLINICAL TESTING

No animal testing was submitted to support the substantial equivalence of KardioScreen to PADECG. The following non-clinical testing was performed to support the substantial equivalence of KardioScreen to the predicate device:

- Electrocardiograph safety and performance
- Electrical safety
- Electromagnetic compatibility (EMC)
- Wireless co-existence testing
- Software verification and validation
- Usability validation
- Biocompatibility

VIII. PERFORMANCE DATA – CLINICAL TESTING

No clinical data were submitted to support the substantial equivalence of KardioScreen to PADECG.

IX. CONCLUSIONS

Based on the indications for use, technological characteristics, results of non-clinical testing, and comparison to the predicate device, KardioScreen has been shown to be substantially equivalent to a legally marketed predicate device.