February 28, 2018

Shenzhen Coreray Technology Co., Ltd.
% Field Fu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
No. 55 Shizhou zhong Road
Nanshan District, Shenzhen
Guangdong, China 518100

Re: K172797
Trade/Device Name: ECG Cable/Leadwires
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient transducer and electrode cable (including connector)
Regulatory Class: Class II
Product Code: DSA
Dated: January 24, 2018
Received: January 30, 2018

Dear Field Fu:

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.

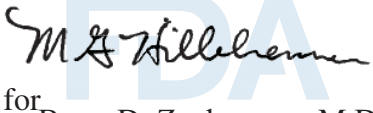
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

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.

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,



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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K172797

Device Name
ECG Cable/Leadwires

Indications for Use *(Describe)*
The ECG Cable/Leadwires is intended to be used with ECG. The ECG Cable/Leadwires is used to connect electrodes placed at appropriate sites on the patient to ECG for general monitoring and/or diagnostic evaluation by health care professional.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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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VOL 05 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted As Required by requirements of SMDA and 21 CFR §807.92.

5.1 Administrative Information

Date of Summary prepared	Aug 17, 2017
Manufacturer information	Company title: Shenzhen Coreray Technology Co., Ltd Company address: ChuangYe Technology Park,1th Dong Huan Road, Longhua New District, Shenzhen, 510000 P.R China. P.C.:518109 Contact person: Simon Fan Phone: +86-755-28839229 Fax: +86-755-28839229 E-mail: manager@core-ray.com
Submission Correspondent	Shenzhen Joyantech Consulting Co., Ltd. Address: Room 1122#, International Mayors Communication Centre, NO. 55 Shizhou middle road , Nanshan District, Shenzhen Contact person: Mr. Field Fu E-Mail: field@cefda.com; cefda13485@163.com
Establishment registration number	

5.2 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	ECG Cable/Leadwires
Model:	
Classification name:	Cable, Transducer And Electrode, Patient,

	(Including Connector)
Review Panel:	Cardiovascular
Product Code:	DSA
Device Class:	II
Regulation Number:	870.2900

5.3 Predicate Device Information

Sponsor:	SHENZHEN MED-LINK ELECTRONICS TECH CO., LTD.
Device:	CABLE/ LEAD-WIRE
510(K) Number:	K120010

5.4 Device Description

The ECG Cable/Leadwires is comprised of Plug, cable/leadwires and connector. The device is used to transmit ECG signals from electrodes which are affixed to the patient's body for both diagnostic and monitoring purposes. Each lead wire is attached to ECG patient electrodes. The leadwires connector plugs into one end of the external trunk cable which is plug into an ECG monitor.

5.5 Intended Use/ Indications for Use

The ECG Cable/Leadwires is intended to be used with ECG. The ECG Cable/Leadwires is used to connect electrodes placed at appropriate sites on the patient to ECG for general monitoring and/or diagnostic evaluation by health care professional.

5.6 Technological characteristics of the subject device compared to the predicate device

Predicate Device Information:

510(K) No.: K120010
Common name: Cable / lead-wire
Classification name: Cable, Transducer and Electrode, Patient, (Including Connector)
Production regulation: 21 CFR §870.2900

Product code: DSA
Panel: Cardiovascular

Comparison to predicate device:

Elements of Comparison	Proposed device	Predicate device K120010	Remarks
Product Code	DSA	DSA	Same
Regulation Number	870.2900	870.2900	Same
Classification	II	II	Same
Indication for Use	Shenzhen Coreray ECG Cable/Leadwires is intended to be used with ECG. The ECG Cable/Leadwires is used to connect electrodes placed at appropriate sites on the patient to ECG for general monitoring and/or diagnostic evaluation by health care professional.	Shenzhen Med-link Cable/lead-wire are intended to be used with ECG, EKG, SpO2 and invasive Blood Pressure monitoring devices. The Cable/lead-wire are used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by health care professional.	Same as ECG/EKG cable/ lead-wire.
Patent Usage	Reusable	Reusable	Same
Anatomical sites	Attached to electrodes placed at standard specified locations on chest wall	Attached to electrodes placed at standard specified locations on chest wall	Same
Patient end termination	Clip, Snap	Clip, Snap	same
Leadwire material	TPU	Shielded & Unshielded Copper with PVC or TPU Jacket	TPU is same.
Sterile	Non sterile	Non sterile	same
Biocompatibility	No cytotoxicity, No irritation, No sensitization	No cytotoxicity, No irritation, No sensitization	SE
Electrical Performance and Safety	Comply with AAMI/ANSI EC53: 2013 IEC 60601-1:2005+CORR.1: 2006+CORR. 2:2007+AM1: 2012	Comply with ANSI/AAMI EC 53:1995/(R)2001 IEC 60601-1:1998; Am1; A2:1995	SE

5.7 Brief discussion of the nonclinical tests

ECG Cable/Leadwires conforms to the following standards:

IEC 60601-1:2005+CORR.1:2006+CORR.2007+A1:2012 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.

AAMI / ANSI EC53:2013, ECG Trunk Cables and Patient Leadwires.

ISO 10993-1:2009, Biological Evaluation Of Medical Devices - Part 1: Evaluation And Testing Within A Risk Management Process.

5.8 Brief discussion of clinical tests
N/A.

5.9 Other information (such as required by FDA guidance/Test)
N/A.

5.10 Conclusions
Based on the above information, the subject device and the predicate device have the same intended use and same technological characteristics; we conclude the subject device, ECG Cable/ Leadwires, is substantially equivalent to the predicate device.