DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 24, 2017

APK Technology Co., Ltd.
% Ms. Diana Hong
General Manager
Mid-link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120 CN

Re: K170536
Trade/Device Name: ECG Disposable Lead Wires
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: February 20, 2017
Received: February 23, 2017

Dear Ms. Diana Hong:

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170536

Device Name
ECG Disposable Lead Wires

Indications for Use *(Describe)*
The ECG Disposable Lead Wires are intended to be used with ECG. The lead wire 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)

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K170536

1. Date of Preparation: 03/02/2017

2. Sponsor Identification

APK Technology Co., Ltd.
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Fu (Alternative Contact Person)

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Fax: 240-238-7587
Email: info@mid-link.net

Trade Name: ECG Disposable Lead Wires
Common Name: ECG Wire

Regulatory Information

Classification Name: Cable, Transducer and Electrode, Patient, (Including Connector)
Classification: II;
Product Code: DSA
Regulation Number: 870.2900
Review Panel: Cardiovascular

Indication for Use:

The ECG Disposable Lead Wires are intended to be used with ECG. The lead wire 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.

Device Description

The ECG Disposable Lead Wires are comprised of patient end termination, leadwire and patient leadwire 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 lead wire connector plugs into one end of the external trunk cable which are plug into an ECG monitor.

4. Identification of Predicate Device

510(k) Number: K120010
Product Name: Cable/lead-wire

5. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009 Biological Evaluation of Medical Devices- Part 5: Tests For In Vitro Cytotoxicity.
- ISO 10993-10:2010 Biological Evaluation of Medical Devices- Part 10: Tests for Irritation and Skin Sensitization.
- AAMI/ANSI EC53: 2013 ECG Trunk Cables and Patient Leadwires
- IEC 60601-1:2005+CORR.1: 2006+CORR. 2:2007+AM1: 2012, Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance

6. Clinical Test Conclusion

No clinical study is included in this submission.

7. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device		Predicate Device K120010		Remark
Product Code	DSA		DSA		SE
Regulation Number	870.2900		870.2900		SE
Classification	II		II		SE
Indication for Use	The ECG Disposable Lead Wires are intended to be used with ECG. The lead wire 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.		Similar
Anatomical sites	Attached to electrodes placed at standard specified locations on chest wall or extremities		Attached to electrodes placed at standard specified locations on chest wall		Similar
Patient end termination	Clip, Snap		Clip, Snap		Same
Leadwire material	Polyvinyl chloride (PVC)		Shielded & Unshielded Copper with PVC or TPU Jacket		Similar
Sterile	Non sterile		Non sterile		Same
Biocompatibility	Cytotoxicity	No cytotoxicity	Cytotoxicity	No cytotoxicity	Same
	Skin Irritation	No irritation	Skin Irritation	No irritation	
	Sensitization	No sensitization	Sensitization	No sensitization	
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		Same

8. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.