January 30, 2019

Orantech Inc.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 China

Re: K182327
Trade/Device Name: Patient Cables and Leadwires, Disposable ECG Leadwires
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: December 26, 2018
Received: December 31, 2018

Dear 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Jessica E. Paulsen -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182327

Device Name
Patient Cables and Leadwires, Disposable ECG Leadwires

Indications for Use *(Describe)*
The device is 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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Tab #7 510(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: K182327

1. Date of Preparation: 01/30/2019

2. Sponsor Identification

Orantech Inc
Zone # A, 4F, 1st Bld, 7th Industrial Zone, Yulv Community, GongMing, Guangming New District, Shenzhen, China 518106

Establishment Registration Number: 3013783488

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3. Designated Submission Correspondent

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

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4. Identification of Proposed Device

Trade Name: Patient Cables and Leadwires
Disposable ECG Leadwires
Common Name: ECG Wire

Regulatory Information

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

Intended Use Statement:

The device is 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 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 trunk cable which are plug into an ECG monitor. The proposed devices are available in disposable and reusable two types.

5. Identification of Predicate Device

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

6. Non-Clinical Test Conclusion

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

- ISO10993-1:2009 Biological Evaluation of Medical Devices-Part 1: Evaluation and Testing within

a Risk Management Process

- ISO10993-5:2009 Biological Evaluation of Medical Devices-Part 5: Tests for in Vitro Cytotoxicity;
- ISO10993-10:2010 Biological Evaluation of Medical Devices-Part10: Tests for Irritation and Skin Sensitization;
- 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;;
- ANSI/AAMI EC53:2013 ECG Trunk Cables and Patient Leadwires;

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device		Predicate Device K120010	
Product Code	DSA		DSA	
Regulation Number	870.2900		870.2900	
Classification	II		II	
Intended Use	The device is 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.	
Anatomical sites	Attached to electrodes placed at standard specified locations on chest or extremities		Attached to electrodes placed at standard specified locations on chest wall	
Patient end termination	Clip, Snap		Clip, Snap	
Sterile	Non sterile		Non sterile	
Leadwire material	PA6/PA66/TPU/ABS/PC/TPE		Shielded & Unshielded Copper with PVC or TPU Jacket	
Biocompatibility	Irritation	No irritation	Skin Irritation	No irritation
	Skin Sensitization	No sensitization	Sensitization	No sensitization
	Cytotoxicity	No cytotoxicity	Cytotoxicity	No cytotoxicity
Electrical Safety	Comply with IEC 60601-1 and EC53		Comply with IEC 60601-1 and EC53	

9. 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.