DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 24, 2016

Shenzhen Caremed Medical Technology Co., Ltd.
Xinlin Xiao, QA Manager
Zone B, 3/f, 11 Building, Hebei Industrial Area,
Longhua Office, Longhua New D
Shenzhen, 518021
CHINA

Re: K153188
Trade/Device Name: Caremed Patient Cable and Leadwires, Models: 2585P, MQB5-90S, MQ-2586, E10R-SH1-N, E10R-MQ and MQ10-LN
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: September 2, 2016
Received: September 16, 2016

Dear Xinlin Xiao:

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.

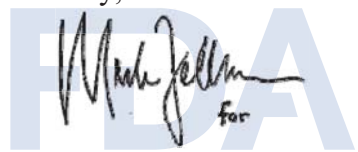
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's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



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)*
K153188

Device Name
Caremed patient cable and leadwires, Models 2585P, MQB5-90S, MQ-2586, E10R-SH1-N, E10R-MQ, MQ10-LN

Indications for Use *(Describe)*
The subject device is intended for use only by trained healthcare professionals for measurement of a patient's ECG for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5 510(K) Summary

1. Prepared Date: 2016/9/2

2. Submitter Information

Name	Shenzhen Caremed Medical Technology Co., Ltd.
Address	Zone B, 3/F, 11 Building, Hebei Industrial Area, Longhua office, Longhua New District, Shenzhen,China
Tel	0086-755-27184369
Fax	0086-755-27186486

3. Contact Person

Contact person	Xinlin Xiao
Title	QA manager
Address	Zone B, 3/F, 11 Building, Hebei Industrial Area, Longhua office, Longhua New District, Shenzhen，China
Tel	0086-755-27184369
Fax	0086-755-27186486
E-mail	cm001@szcaremed.com

4. Proposed Device Information

Trade Name	Caremed patient cable and leadwires
Model	2585P, MQB5-90S, MQ-2586, E10R-SH1-N, E10R-MQ, MQ10-LN
Common name	Patient Transducer and electrode cable (including connector)
Regulatory class	Ⅱ
Production regulation	21 CFR §870.2900
Product code	DSA
Panel	Cardiovascular

5. Predicate Device Information

510(K)No.	Trade Name/model	Submitter
K142489	Unimed Disposable ECG lead wires	Unimed Medical Supplies,Inc.

6. Device description

The Caremed patient cable and lead wires including trunk cable and leadwires, are intended use for transmitting signals from patient surface electrodes to various

electrocardiograph recorders/monitors for both diagnostic and monitoring purposes. The type of devices are common to both industry and to most medical establishments. The system is designed to provide a family of lead wires that will link the patient and the compatible patient trunk cable system.

7. Intended use

The subject device is intended for use only by trained healthcare professionals for measurement of a patient's ECG for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment.

8. Comparison to predicate device

Comparison item	Subject Device Applied present	Predicate Device K142489
Intended use &Indications for Use	The subject device are intended for use only by trained healthcare professionals for measurement of a patient's ECG for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment.	The unimed disposable ECG lead wires are intended for use only by trained healthcare professionals for measurement of a patient's ECG for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment. These leadwires are intended for short-term use only (an average patient stay of 5 days).
Anatomical Sites	Attached to electrodes placed at standard specified locations on chest wall and extremities	Attached to electrodes placed at standard specified locations on chest wall and extremities
Design /Appearance	Cables with "grabber,snap&needle" configuration of ECG electrode connector (distal connector) and common "header" connection (proximal connector)	Cables with "grabber/snap" configuration of ECG electrode connector (distal connector) and common "header" connection (proximal connector)
Sterility	Supplied non-sterile	Supplied non-sterile
Usage	Reusable	Single patient use
Material	PA66,PVC,ABS	PA66,PVC,ABS
Cable Length	0.9m/3.4m/2.5m/2.4m	0.9m/3.4m

Cable Construction	Flexible shielded multi conductor electrical cable	Flexible shielded multi conductor electrical cable
Wire Color	Grey	White
Leadwire Construction	Shielded copper leadwire with polymer jacket	Shielded copper leadwire with polymer jacket
Lead number	5&10	3,5&6
Proximal connector Design	Compatible to MultiLink yoke design	Compatible to MultiLink yoke design
Distal connector Design	"Grabber",”Snap”&"Needle"electrode connectors labeled LL(red),RA(white),RL(green),LA(black)&,V(brown) or socket connecting with lead wires	"Grabber"or”Snap”electrode connectors are labeled LL(red),RA(white),RL(green),LA(black)&,V(brown)
Conformance standard	IEC60601-1(Safety) EC53(Performance) ISO10993-5,-10(Biocompatibility)	IEC60601-1(Safety) EC53(Performance) ISO10993-5,-10(Biocompatibility)

From the comparison form above, both devices have the same Intended use &Indications for Use Anatomical Sites, Design /Appearance, Sterility, Material,Cable Construction,& Conformance standard.

But in Usage,cable length, Lead number& Distal connector Design item,both devices have some difference,But these units meet the requirements of EC53 and IEC60601-1, so these difference does not bring any safety and effectiveness problem.

9. Clinical test data

Not applied

10. Substantial Equivalence Statement

The subject device meets the following the recognized standards:

- ANSI/ANMM EC53-1995 (R)2001, R(2008) ECG Cables and Leadwires (except4.3.1)
- ANSI/AAMI EC13 Cardiac monitors, heart rate meters and alarms (only product markings, chapter 4.1.1.5),2002
- Part 898: Performance Standard for Electrode Lead Wires and Patient Cables
- IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety, 1988+A1:1991+A2:1995
- ISO 10993-5, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity, 2010

11. Discussion

Based on the comparison ,analysis, and the submitted performance data, the proposed device is claimed to be Substantially Equivalent (SE) to the predicate devices in K142489.