February 5, 2021

JKH USA, LLC
Bill Dai
Manager
14271 Jeffrey Rd. #246
Irvine, California 92620

Re: K203635
Trade/Device Name: Patient Monitoring Cables
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer And Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: December 9, 2020
Received: December 14, 2020

Dear Bill Dai:

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 Kozen
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
N/A

Device Name
Patient Monitoring Cables

Indications for Use *(Describe)*
The Patient Monitoring Cables are intended to be used with ECG, EKG, Spo2 and BP monitoring devices. The Patient Monitoring Cables 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 heath 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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"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."

510(k) Summary

Submitter:	Name: JKH USA, LLC Mailing Address: 14271 Jeffrey Rd. #246, Irvine, CA 92620
Contact Person:	Name: Bill Quanqin Dai Phone Number: 909-929-9896 Email Address: Bill@jkhUSA.com
Date Prepared:	12/09/2020
Device Trade Name:	Patient Monitoring Cables
Device Common Name:	Cable, Transducer and Electrode, Patient, (Including Connector)
Model:	PDX-2595, PDX-90S, PMQ-2586, PMQ3-90P, PMQ5-90P, PAA-2585, PAA5-90P, P2540S, PD5-90S, PE1O-HP-B, PE10-MQ12-B, PU708-O1, PU708-21, PU708-40, PBC-6P-UT, PHT3-90DS, PDG5-90DS, PSMB3-90DP, PHPA5-90DP, P2385DS, PMR5-90DS, PAP5-90DS, PMQ3-90DS, PNKB6-90DS, PD3-90DS, PAAB5-90DS, PDT5-90DS, P2586DP, PMQB6-90DS, PAAB3-90DP, PAP6-90DS, PDG3-90DP, PAT5-90DP, PMR5-90DP, PDT3-90DS, PDG6-90DS, PAT3-90DS, P2396DS, P2386DP, PHT5-90DS, PSM5-90DS, P2585DP, PNKB3-90DS, PD5-90DP, PAP3-90DP, P2596DS, P2312DP, P2512DP, PHP3-90DS, PMQ5-90DS
Classification Names: **Regulation Number:** **Product Code:**	Cable, Transducer and Electrode, Patient, (Including Connector) 21 CFR 870.2900 DSA
Predicate Device 1: **510(k) Number:** **Device Name:** **Manufacturer:**	 K082959 Patient monitoring Cables for ECG, EKG, SpO2 and Blood Pressure Monitors UNIMED MEDICAL SUPPLIES INC
Predicate Device 2: **510(k) Number:** **Device Name:** **Manufacturer:**	 K142489 Unimed Disposable ECG Lead Wires UNIMED MEDICAL SUPPLIES INC

Description of Devices:

Patient Monitoring Cables are the replacements for similar cables manufactured by Original Equipment Manufacturers (OEM) for their respective monitors.

It is a non-patient-contact, insulated, shielded, electrical cord with a connector (plug) at both ends designed to transmit electrical power and/or signal (data) between medical devices (e.g., to connect ECG electrodes, SpO2 sensor, IBP transducer to a patient monitor). It is not intended to connect to the mains (i.e., not a mains power cable), does not generate any type of power and/or signal, and has no additional non-electrical conducting or processing

functionality.

Intended Use:

The Patient Monitoring Cables are intended to be used with ECG, EKG, Spo2 and BP monitoring devices. The Patient Monitoring Cables 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 heath care professional.

Comparison to predicate device:

The subject and predicate devices are exactly the same, and there is no any difference between them.

Table 1 Substantial Equivalence Table

Description	**Subject Device**	**Predicate Device (K082959 and K142489)**
Intended use	The Patient Monitoring Cables are intended to be used with ECG, EKG, Spo2 and BP monitoring devices. The Patient Monitoring Cables 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 heath care professional.	The Unimed patient cables and lead wires are intended to be used with ECG, EKG, Spo2 and BP monitoring devices. The patient cables and lead wires 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 heath care professional.
Prescription/ over-the-counter use	Prescription	Prescription
Design/Appearance	Cables with various connectors(monitor, trunk/lead wire, electrode grabber & snapper)	Cables with various connectors(monitor, trunk/lead wire, electrode grabber & snapper)
Cable length	Various specified standard lengths	Various specified standard lengths
Material	Tin copper, PA66, PVC, ABS	Tin copper, PA66, PVC, ABS
Usage	Reusable and disposable	Reusable and disposable
Sterile	Non-sterile	Non-sterile
Conformance standard	IEC60601-1(Safety) EC53(Performance) ISO 10993-5, -10(Biocompatibility)	IEC 60601-1(Safety) EC53(Performance) ISO 10993-5, -10(Biocompatibility)

Non-clinical test data:

The subject device meets the following the recognized standards:

- IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety
- ANSI AAMI EC53 ECG trunk cables and patient lead wires
- ISO 10993-1 Biological evaluation of medical devices-Part 1: Evaluation and testing within

a risk management process

- ISO 10993-5, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10, Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity

The proposed device belongs to skin contact, and the contact duration is less than 30d. Biocompatibility tests have been conducted on proposed device, including cytotoxicity, sensitization, and skin irritation. The test results show that the proposed device has no cytotoxicity, sensitization, or skin irritation.

Clinical test data:

The subject and predicate devices are exactly the same. Since the cables are identical, no further clinical testing is necessary..

Substantial Equivalence:

The subject and predicate devices are exactly the same. The cables are identical to the cleared version and are not modified. Therefore, the subject device is substantially equivalent to the predicate device