January 6, 2021

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

Re: K203652
Trade/Device Name: Blood Pressure Cuff

Reusable Blood Pressure Cuff models: PU1883S, PU1883D, PU1882S, PU1882D, PU1881S, PU1881D, PU1885S, PU1885D, PU1880S, PU1880D, PU1886S, PU1886D, PU1869S, PU1869D, PU1889S, PU1889D, PU1884S, PU1884D.

Disposable Blood Pressure Cuff models: PU1710S, PU1720S, PU1730S, PU1740S, PU1750S, PU1760S, PU1770S, PU1790S, PU1710D, PU1720D, PU1730D, PU1740D, PU1750D, PU1760D, PU1770D, PU1790D, PU1781S, PU1782S, PU1783S, PU1784S, PU1785S, PU1781D, PU1782D, PU1783D, PU1784D, PU1785D.

Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: December 2, 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,

for LT Stephen Browning
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)*
K203652

Device Name
Blood Pressure Cuff

Indications for Use *(Describe)*
The Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

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.

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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:	12/02/2020
Device Trade Name:	Blood Pressure Cuff
Device Common Name:	Blood Pressure Cuff
Classification Names:	Blood Pressure Cuff
Regulation Number:	21 CFR 870.1120
Product Code:	DXQ
Predicate Device 1:	
510(k) Number:	K112544
Device Name:	Unimed Blood Pressure Cuff
Manufacturer:	UNIMED MEDICAL SUPPLIES INC
Predicate Device 2:	
510(k) Number:	K120364
Device Name:	Unimed Disposable Blood Pressure Cuff
Manufacturer:	UNIMED MEDICAL SUPPLIES INC

Description of Devices:

The device comprises tubing attached to an inelastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure. The device tubing is connected to a non-invasive blood pressure measurement system.

The subject device is categorized into two types of models according to its reusability. Refer to the master list of models below.

Reusable Blood Pressure Cuff models: PU1883S, PU1883D, PU1882S, PU1882D, PU1881S, PU1881D, PU1885S, PU1885D, PU1880S, PU1880D, PU1886S, PU1886D, PU1869S, PU1869D, PU1889S, PU1889D, PU1884S, PU1884D.

Disposable Blood Pressure Cuff models: PU1710S, PU1720S, PU1730S, PU1740S, PU1750S, PU1760S, PU1770S, PU1790S, PU1710D, PU1720D, PU1730D, PU1740D, PU1750D, PU1760D, PU1770D, PU1790D, PU1781S, PU1782S, PU1783S, PU1784S, PU1785S, PU1781D, PU1782D, PU1783D, PU1784D, PU1785D.

Indications for Use:

The Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

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 (K112544 and K120364)**
Indications for use	The Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile. It is available in neonatal, pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	The Unimed Blood Pressure Cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.
Prescription/ over-the-counter use	Prescription	Prescription
Target population	Adults/Pediatrics/neonatal	Adults/Pediatrics/neonatal
Application site	Arm or leg	Arm or leg
Material	Reusable Cuffs: PU Synthetic Leather Reusable Cuffs: PVC composite nonwoven Bladder: Transparent Polyurethane (TPU Film) Tubing: PVC Hook: Molded Nylon Loop: Nylon	Reusable Cuffs: PU Synthetic Leather Reusable Cuffs: PVC composite nonwoven Bladder: Transparent Polyurethane (TPU Film) Tubing: PVC Hook: Molded Nylon Loop: Nylon
Tube Configuration	One or two tube	One or two tube
Repeated inflation	For reusable cuffs: 10,000 inflations 3,000 hook and loop closures	For reusable cuffs: 10,000 inflations 3,000 hook and loop closures
Pressure limits	0-300mmHg	0-300mmHg
Usage	Reusable and disposable	Reusable and disposable
Sterile	Non-sterile	Non-sterile
Standards met	ISO 81060-1 ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 81060-1 ISO 10993-1 ISO 10993-5 ISO 10993-10

Non-clinical test data:

The subject device meets the following the recognized standards:

- ISO 81060-1 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type
- 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 30 days. Biocompatibility tests have been conducted on the proposed device, including cytotoxicity, sensitization, and skin irritation. The test results show that the proposed device has no issue of cytotoxicity, sensitization, or skin irritation.

Clinical test data:

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

Substantial Equivalence:

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