May 6, 2026

Nihon Kohden Corporation
% Charlemagne Chua
Senior Manager, Regulatory Affairs
Nihon Kohden America, LLC
15353 Barranca Pkwy.
Irvine, California 92618

Re: K260747
Trade/Device Name: YP-710T Series NIBP Cuff;YP-840T Series Disposable Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: March 6, 2026
Received: March 6, 2026

Dear Charlemagne Chua:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

STEPHEN C. BROWNING -S

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
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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)*
K260747

Device Name
YP-710T Series NIBP Cuff; YP-840T Series Disposable Cuff

Indications for Use *(Describe)*

YP-710T Series NIBP Cuff

The NIBP Cuff (YP-710T series) is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile and reusable. It is available in pediatric and adult sizes. The device is intended for use by qualified medical personnel and within a medical facility.

YP-840T Series Disposable Cuff

The Disposable Cuff (YP-840T series) is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile and disposable (single-use). It is available in pediatric and adult sizes. The device is intended for use by qualified medical personnel and within a medical facility.

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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510(k) SUMMARY

Administrative Information

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Subject Device Information

Submission Type:	Traditional 510(k)
Common Device Name:	Blood Pressure Cuff
Regulation Medical Specialty:	Cardiovascular
Classification Panel:	Cardiovascular
Product Codes:	DXQ
Premarket Review:	Cardiac Electrophysiology, Diagnostics, and Monitoring Devices (DHT2A)
Regulation Number:	870.1120
Classification:	Class II
Decision Type:	510(k)
Proprietary Name:	YP-710T series NIBP Cuff YP-840T series Disposable Cuff
Reason for 510(k) Submission:	Modification to an Existing Device and Introduction of New Device
Original 510(k) / Predicate:	SOFT-CUF Blood Pressure Cuff (K120125)
Predicate Manufacturer:	GE Medical Systems Information Technologies, Inc.
Submission Date:	March 6, 2026

1. PRODUCT DESCRIPTION

The YP-710T and YP-840T series are blood pressure cuffs that are applied to the patient's upper or lower limb and connected to a Nihon Kohden host device to measure blood pressure non-invasively. The cuffs are inflated using air pressure supplied from the connected host device.

The YP-710T series is a reusable cuff, intended for repeated use with multiple patients. The YP-840T series is a disposable cuff, intended for single use only. Each series comprises six (6) models based on cuff size. In addition, each model is available with two (2) connector options: A locking connector (twist type) or a small-bore connector compliant with IEC 80369-5 requirements. These are distinguished using different catalog numbers.

2. INDICATION FOR USE / INTENDED USE

YP-710T Series

Intended Use: The NIBP Cuff (YP-710T series) is used to measure non-invasive blood pressure.

Indication for Use: The NIBP Cuff (YP-710T series) is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile and reusable. It is available in pediatric and adult sizes. The device is intended for use by qualified medical personnel and within a medical facility.

YP-840T Series

Intended Use: The Disposable Cuff (YP-840T series) is used to measure non-invasive blood pressure.

Indication for Use: The Disposable Cuff (YP-840T series) is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile and disposable (single-use). It is available in pediatric and adult sizes. The device is intended for use by qualified medical personnel and within a medical facility.

3. SUBMISSION SCOPE

Nihon Kohden (NK) is requesting market clearance for a modified Nihon Kohden device, the modification to an existing device and introduction of new device. The modification is replace the current twist type connector with a small bore connector (compliant with IEC80369-5).

4. COMPARISON WITH THE PREDICATE / REFERENCE DEVICE

4.1 Subject Device Information

Table 1 provides the regulation and classification for the subject device.

Table 1 Regulatory Information on YP-710T Series and YP-840T Series

Device	Regulation	Product Code	Device Classification	Classification
YP-710T Series	§870.1120	DXQ	Blood pressure cuff.	Class II
YP-840T Series	§870.1120	DXQ	Blood pressure cuff.	Class II

4.2 Predicate / Reference Device Information

Table 2 lists the basic information about the predicate devices and reference device including 510(k) number, device name, 510(k) holder, and clearance date. Regulatory information used for comparison is provided in Table 3

Table 2 Predicate Device General Information

Device	Predicate/Reference Device General Information			
	510(k) Number	Device Name	510(k) Holder	Clearance Date
SOFT-CUF	K120125	SOFT-CUF	GE Medical Systems Information Technologies, Inc.	October 3, 2012

Table 3 Predicate Device Regulatory Information

Device	Regulation	Product Code	Device Classification	Classification
SOFT-CUF	§870.1120	DXQ	Blood Pressure Cuff	Class II

4.3 Comparison Table

Table 4 Comparison Table of the YP-710T and YP-840T Series and Predicate Device

Description	Predicate Device SOFT-CUF Blood Pressure Cuff K120125	Subject Device YP-710T series YP-840T series	Comparison
Manufacturer	GE Medical Systems Information Technologies, Inc.	Nihon Kohden Corporation	Different
Product Code	DXQ	DXQ	Same
Indications for Use	GE CRITIKON blood pressure cuffs are accessories used in conjunction with noninvasive blood pressure (NIBP) measurement systems. SOFT-CUF and CLASSIC-CUF cuffs and inflation systems are non-sterile and limited reuse (may be single-patient use or optional limited reuse). They are available in neonatal, pediatric and adult sizes. The devices are not designed, sold or intended for use except as indicated.	**YP-710T series** The NIBP Cuff (YP-710T series) is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile and reusable. It is available in pediatric and adult sizes. The device is intended for use by qualified medical personnel and within a medical facility. **YP-840T series** The Disposable Cuff (YP-840T series) is an accessory used in conjunction with non-invasive blood pressure measurement systems. The cuff is non-sterile and disposable (single-use). It is available in pediatric and adult sizes. The device is intended for use by qualified medical personnel and within a medical facility.	Different
Use Characteristics	Non-sterile, single patient use or limited reuse	**YP-710T series** Non-sterile, reprocessed for reuse **YP-840T series** Non-sterile, disposable (single-use)	Different
Population	Adult, pediatric, neonatal	Adult and pediatric	Different
Intended Use	Indirect measurement of blood pressure	**YP-710T series** The NIBP Cuff (YP-710T series) is used to measure non-invasive blood pressure. **YP-840T series**	Same

Description	Predicate Device SOFT-CUF Blood Pressure Cuff K120125	Subject Device YP-710T series YP-840T series	Comparison
		The Disposable Cuff (YP-840T series) is used to measure non-invasive blood pressure.	
Environmental Specifications			
Operating Conditions	**Temperature** 0° C to 46° C **Relative Humidity** 15% to 90% humidity, non-condensing	**Temperature** 10 to 40ºC (50 to 104ºF) **Relative Humidity** 15 to 85% (non-condensing)	Different
Storage Conditions	**Temperature** -20° C to 55° C **Relative Humidity** 0% to 95% humidity, non-condensing	**YP-710T Series** **Temperature** -20 to +60ºC (–4 to +140ºF) **Relative Humidity** 10 to 95% (non-condensing) **YP-840T Series** **Temperature** -20 to +65ºC (–4 to +149ºF) **Relative Humidity** 10 to 95% (non-condensing)	Different
Physical Specifications			
Limb Circumference (Ranges in cm)	Neonatal #1 (3-6) Neonatal #2 (4-8) Neonatal #3 (6-11) Neonatal #4 (7-13) Neonatal #5 (8-15) Infant (8-13) Child (12-19) Child Long (12-19) Small Adult (17-25) Small Adult Long (17-25) Adult (23-33) Adult Long (23-33) Large Adult (31-40) Large Adult Long (31-40) Thigh (38-50)	Infant (8-13) Child (13-18) Small Adult (18-23) Adult (23-33) Large Adult (33-45) Thigh (45-55)	Different
Bladder Size	Various bladder sizes for neonate, pediatric and adult populations	Various bladder sizes for pediatric and adult populations	Different
Cuff Connector Configurations	Adult and Pediatric 2-Tube configuration: • Screw Connector • Sub-Miniature Connector • Mated Subminiature Connector	· Legacy locking connector (twist type) · Small-bore connector	Different

Description	Predicate Device SOFT-CUF Blood Pressure Cuff K120125	Subject Device YP-710T series YP-840T series	Comparison
	• Dual CLICK-IT (branded as "DINACLICK") Connector Adult and Pediatric 1-Tube configuration: • Bayonet Connector • Screw • Sub-Miniature Connector Neonatal • 1-Tube and 2-Tube Male Slip Luer Taper • 1-Tube and 2-Tube SNAP-IT (branded as "NeoSnap") Connectors		
Materials			
Cuff / Integrated Bladder / Ink	SOFT-CUF: Laminate of polyester / polyvinyl chloride/ SOFT-CUF: Zephyron-Ion Solvent Based	**YP-710T Series** Cuff: Polyester Tube: Polyvinyl Chloride **YP-840T Series** Cuff: Laminate of polyester and polyvinyl chloride Tube: Polyvinyl Chloride	Different
Compatibility			
Device	Single / dual tubes, adaptors and bulb / valve assemblies for use with manual and automated sphygmomanometers.	Connect to the host device with automated NIBP monitoring capability (automated sphygmomanometer) via dual-tube air hose.	Different
Performance Specifications			
Leak Rate	Maximum allowable pressure loss rate is 0.6 sccm (standard cubic cm per minute)	Not specified	Different
Air Leakage	Less than 4mmHg/min	Less than 4mmHg/min	Same
Pressure Range	0-300 mmHg	0-300 mmHg	Same
Standards Compliance			
Automated/Manual Sphygmomanometers	SP10:2002/A1:2003/A2:2006 EN 1060-1:1995/A1:2002/A2:2009 (applicable sections) EN 1060-2:1995/C1:2002/A1:2009 (applicable sections)	IEC 80601-2-30:2018 (applicable sections) ISO 81060-1:2007 (applicable sections)	Different

Description	Predicate Device SOFT-CUF Blood Pressure Cuff K120125	Subject Device YP-710T series YP-840T series	Comparison
	IEC 80601-2-30:2009 (applicable sections) ISO 81060-1:2007 (applicable sections)		
Biocompatibility Standard Compliance	Cuff fabric, ink, loop evaluated per ISO10993-1:2009 • Irritation • Sensitization • Cytotoxicity	ISO10993-1:2018 Irritation • Sensitization • Cytotoxicity	Different

5. PERFORMANCE

5.1 Summary of Non-Clinical Performance Testing

Nihon Kohden conducted non-clinical bench performance testing as part of the design verification and validation activities. The YP-710T series (NIBP Cuffs) and YP-840T series (Disposable Cuffs) were evaluated for reprocessing & shelf-life, biocompatibility, and usability performance. The same test methods and specifications were used as for the predicate device, establishing equivalency with the predicate devices. These tests were performed according to the international and FDA-recognized consensus standards listed in Table 7.

Table 7 Applied Standards and Guidance List for the YP-710T Series (NIBP Cuffs) and YP-840T Series (Disposable Cuffs)

Rec. No.	Standard	Description
5-125	ISO 14971:2019	Medical devices - Application of risk management to medical devices
2-258	ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
2-245	ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
2-296	ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
2-291	ISO 10993-23: 2021	Biological evaluation of medical devices - Part 23: Tests for irritation
2-289	ISO 10993-12: 2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
3-123	IEC 80601-2-30: 2018	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers Partial compliance
3-96	ISO 81060-1: 2007	Non-invasive sphygmomanometers Part 1: Requirements and test methods for non-automated measurement type

Rec. No.	Standard	Description
		Partial compliance
5-107	IEC 80369-5: 2016	Small-bore connectors for liquids and gases in healthcare applications Part 5: Connectors for limb cuff inflation applications It only applies to the YP-710T and YP-840T series with a small-bore connector.
14-575	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

6. SUBSTANTIAL EQUIVALENCE DISCUSSION

The comparison of the YP-710T series (NIBP Cuffs) and YP-840T series (Disposable Cuffs) to its predicate device (SOFT-CUF, K120125 and the discussion of the key aspects are presented in the following sections.

6.1 Discussion of Intended Use

In comparing the Intended Use between the YP-710T series (NIBP Cuffs) and YP-840T series (Disposable Cuffs) and its predicate device, the Intended Use are the same.

6.2 Discussion of Indications for Use

In comparing the Indications for Use between the YP-710T series (NIBP Cuffs) and YP-840T series (Disposable Cuffs) and its predicate device, both are accessories noninvasive blood pressure (NIBP) measuring systems.

6.3 Discussion for Technological Characteristics

The YP-710T series (NIBP Cuffs) and YP-840T series (Disposable Cuffs) and its predicate device have similar technological characteristics.

6.4 Discussion for Design Characteristics

There are slight differences between the YP-710T series (NIBP Cuffs) and YP-840T series (Disposable Cuffs) and the predicate as referenced. The differences are based on design changes to accommodate new design improvement and to ensure compliance with current applicable standards. The changes have been evaluated to ensure there is no impact on the safety and effectiveness of the YP-710T series (NIBP Cuffs) and YP-840T series (Disposable Cuffs).

6.5 Discussion for Compatible Devices

The YP-710T series (NIBP Cuffs) and YP-840T series (Disposable Cuffs) and predicate device require the device to be connected to noninvasive blood pressure (NIBP) measurement systems. The subject device will be used with more Nihon Kohden noninvasive blood pressure (NIBP) measurement systems that have received 510(k) clearance.

6.6 Discussion for Performance Specifications

The YP-710T series (NIBP Cuffs) and YP-840T series (Disposable Cuffs) has been compared and evaluated using the same performance methods and testing criteria as the predicate.

7. CONCLUSION

The results of the substantial equivalence assessment, taken together with non-clinical bench testing and validation demonstrate that the YP-710T series (NIBP Cuffs) and YP-840T series (Disposable Cuffs) do not raise concerns regarding their safety and effectiveness compared to their predicate device and operates in accordance with claimed indications for use. YP-710T series (NIBP Cuffs) and YP-840T series (Disposable Cuffs) are substantially equivalent to the predicate device.