March 14, 2023

GE Medical Systems Information Technologies, Inc.
% Michelle Johnson
Regulatory Affairs Manager
GE Healthcare
9900 Innovation Drive
Wauwatosa, Wisconsin 53226

Re: K230145
Trade/Device Name: One-cuf
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: January 18, 2023
Received: January 18, 2023

Dear Michelle Johnson:

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,

Robert T. Kazmierski -S

for

LCDR 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)*
K230145

Device Name
ONE-CUF

Indications for Use *(Describe)*
The blood pressure cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. It is non-sterile, single-patient use. It is available in 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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In accordance with 21 CFR 807.92 the following summary of information is provided:	
Date:	January 9, 2023
Primary Contact Person:	Michelle Johnson Senior Quality Staff Manager - Regulatory Affairs GE Medical Systems Information Technologies, Inc. Phone: +1 414 429 9263 Email: Michelle.Johnson@ge.com
Secondary Contact Person:	Jennifer Strauther Regulatory Affairs Leader GE Medical Systems Information Technologies, Inc. 9900 Innovation Drive Wauwatosa, WI 53226 Phone: +1 262 330 2112 Email: Jennifer.Strauther@ge.com
Device Trade Name:	ONE-CUF
Common/Usual Name:	Blood Pressure Cuff
Classification Names:	Blood Pressure Cuff
Regulation	21 CFR 870.1120 Blood Pressure Cuff
Classification	II
Product Code:	DXQ
Predicate Device:	SOFT-CUF (K120125)
Intended Use	Indirect measurement of blood pressure
Indications for Use:	The blood pressure cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. It is non-sterile, single-patient use. It is available in pediatric and adult sizes. The cuff is not designed, sold or intended for use except as indicated.

5.1 Device Description:

ONE-CUF blood pressure cuffs are accessories used in conjunction with noninvasive blood pressure (NIBP) measurement systems to obtain a blood pressure measurement.

Blood pressure cuffs are non-sterile and single-patient use and may not be reprocessed for use on additional patients. They are available in pediatric and adult sizes. The devices are not designed, sold or intended for use except as indicated.

Blood pressure cuffs do not include serviceable parts or components.

Non-Invasive Blood Pressure Cuffs incorporate an inflatable non-distensible bladder, sized to encircle a patient's limb. The cuff includes one or two flanges for attaching flexible tubing. This allows air to flow in and out of the cuff bladder for inflation and deflation. Inflation allows for occlusion of an artery to facilitate the measurement of automated non-invasive blood pressure (NIBP). The cuff tubes are terminated with connectors that allow for attachment to a blood pressure hose. This cuff will be offered with two different connection systems, bayonet and DINACLICK.

5.2 Comparison of Technological Characteristics with the Predicate Device

The Non-Invasive Blood Pressure Cuffs employ the same fundamental scientific technology as its predicate device. The differences between the ONE-CUF and the predicate SOFT-CUT do not raise any new or questions on the safety and effectiveness.

Feature/Function	Predicate Device/System Name and 510 (k) SOFT-CUF Blood Pressure Cuff K120125	Proposed Device/System Name ONE-CUF Blood Pressure Cuff	Comparison Result
Intended Use			
• Indications for Use	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.	Indications For Use The blood pressure cuff is an accessory used in conjunction with non-invasive blood pressure measurement systems. It is non-sterile, single-patient use. It is available in pediatric and adult sizes. The cuff is not designed, sold or intended for use except as indicated.	Equivalent.
• Use	Non-sterile, single patient use or limited reuse	Non-sterile, Single patient use	Equivalent
• Population	Adult, pediatric, neonatal	Adult and Pediatric	Equivalent.
• Intended Use	Indirect measurement of blood pressure	Indirect measurement of blood pressure	Identical
Environmental Specifications – Operating Conditions			
• Temperature	0° C to 46° C	0° C to 40° C	Equivalent

Feature/Function	Predicate Device/System Name and 510 (k) SOFT-CUF Blood Pressure Cuff K120125	Proposed Device/System Name ONE-CUF Blood Pressure Cuff	Comparison Result
• Relative Humidity	15% to 90% humidity, non-condensing	15% to 90% humidity, non-condensing	Identical
Environmental Specifications – Storage Conditions			
• Temperature	-20° C to 55° C	-20° C to 55° C	Identical
• Relative Humidity	0% to 95% humidity, non-condensing	0% to 95% humidity, non-condensing	Identical
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 (12-19) Small Adult (17-25) Adult (23-33) Adult Long (23-33) Large Adult (31-40)	Equivalent
• Bladder Size	Various bladder sizes for neonate, pediatric and adult populations	Various bladder sizes for pediatric and adult populations	Equivalent

Feature/Function	Predicate Device/System Name and 510 (k) SOFT-CUF Blood Pressure Cuff K120125	Proposed Device/System Name ONE-CUF Blood Pressure Cuff	Comparison Result
• Cuff Connector Configurations	Adult and Pediatric 2-Tube configuration: • Screw Connector • Sub-Miniature Connector • Mated Subminiature Connector • 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	Adult and Pediatric 2-Tube configuration: • Dual CLICK-IT (branded as "DINACLICK") Connector Adult 1-Tube configuration: • Bayonet Connector	Equivalent.
Materials			
• Cuff / Integrated Bladder	SOFT-CUF: Laminate of polyester / polyvinyl chloride	ONE-CUF: Laminate of polyester / polyvinyl chloride	Equivalent.
• Ink	SOFT-CUF: Zephyron-Ion Solvent Based	ONE-CUF: Zephyron-Ion Solvent Based	Identical.
Compatibility			
• Device	Single / dual tubes, adaptors and bulb / valve assemblies for use with manual and automated sphygmomanometers.	ONE-CUF: Single / dual tubes for use with manual and automated sphygmomanometers.	Equivalent.
Performance Specifications			
• Leak Rate	Maximum allowable pressure loss rate is 0.6 sccm (standard cubic cm per minute)	Maximum allowable pressure loss rate is 0.6 sccm (standard cubic cm per minute)	Identical
• Air Leakage	Less than 4mmHg/min	Less than 4mmHg/min	Identical
• Pressure Range	0-300 mmHg	0-300 mmHg	Identical
Standards Compliance (Applicable Sections)			
• Automated/Manual Sphygmomanometers	SP10:2002/A1:2003/A2:2006	IEC 80601-2-30:2018 (applicable sections) ISO 81060-1:2007 (applicable sections)	Equivalent
• Automated/Manual Sphygmomanometers	EN 1060-1:1995/A1:2002/A2:2009 (applicable sections) EN 1060-2:1995/C1:2002/A1:2009 (applicable sections) IEC 80601-2-30:2009 (applicable sections) ISO 81060-1:2007 (applicable sections)	IEC 80601-2-30:2018 (applicable sections) ISO 81060-1:2007 (applicable sections)	Equivalent

Feature/Function	Predicate Device/System Name and 510 (k) SOFT-CUF Blood Pressure Cuff K120125	Proposed Device/System Name ONE-CUF Blood Pressure Cuff	Comparison Result
Biocompatibility			
Biocompatibility Standard Compliance	Cuff fabric, ink, loop evaluated per ISO10993-1:2009 • Irritation • Sensitization • Cytotoxicity	Cuff fabric and loop evaluated per ISO10993-1:2018 • Irritation • Sensitization • Cytotoxicity	Equivalent

5.3 Determination of Substantial Equivalence:

Summary of Non-Clinical Testing:

The following performance data were provided in support of the substantial equivalence determination.

- Environmental Conditioning
- Leak
- Pressure Capacity
- Mechanical Strength
- Tensile Testing
- Standards
- Biocompatibility

Biocompatibility testing

Biocompatibility testing was performed in accordance with per ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process. In accordance with FDA guidance document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* issued September 4, 2020.

- Chemical characterization
- Cytotoxicity
- Sensitization
- Irritation/intracutaneous reactivity

Compliance with Voluntary Standards

The ONE-CUF Warmer is designed and tested for compliance with the following performance standards:

1. 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
2. ISO 81060-1:2007 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type

Animal Study

The ONE-CUF did not required animal tests to support substantial equivalence.

Clinical Studies

The ONE-CUF did not required clinical tests to support substantial equivalence.

Human Factors Validation

The ONE-CUF performed summative usability to support substantial equivalence.

Conclusion:

Based on the indications for use, technological characteristics, and comparison to predicate devices, the subject ONE-CUF has been shown to be substantially equivalent to legally marketed predicate device.