December 16, 2025

Baxter Healthcare Corporation
Aravinda Yellina
Regulatory Affairs Senior Specialist
One Baxter Parkway
Deerfield, Illinois 60015

Re: K251745
Trade/Device Name: Welch Allyn FlexiPort Blood Pressure Cuffs (FlexiPort Blood Pressure Cuffs)
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: November 7, 2025
Received: November 14, 2025

Dear Aravinda Yellina:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251745

Device Name

Welch Allyn FlexiPort Blood Pressure Cuffs (FlexiPort Blood Pressure Cuffs)

Indications for Use *(Describe)*

Welch Allyn FlexiPort Blood Pressure Cuffs are intended to be used for patient health screening assessment to determine patient's systolic/diastolic blood pressure when used in conjunction with non-automated and automated sphygmomanometers.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Baxter

Section 8-B. 510(K) Summary

OWNER:

Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015

CONTACT PERSON:

Aravinda Yellina
Senior Specialist, Regulatory Affairs
Baxter Healthcare Corporation
One Baxter Parkway
Deerfield, IL 60015

IDENTIFICATION OF THE DEVICE:

Trade/Device Name: Welch Allyn FlexiPort Blood Pressure Cuffs
(FlexiPort Blood Pressure Cuffs)
Classification Panel: 74 Cardiovascular
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ

Table 1. Model number for FlexiPort Blood Pressure Cuffs

Model Number	Name
901043	BLOOD PRESSURE CUFFS, REUSABLE
901044	BLOOD PRESSURE CUFFS, SOFT & VINYL

Predicate Device

Table 2. Predicate Device

Device	Company	Predicate 510(k)	Clearance Date
Welch Allyn FlexiPort Blood Pressure Cuff	Welch Allyn, Inc. (a subsidiary of Baxter Healthcare Corporation)	K070060	December 18, 2007

1

Baxter

DESCRIPTION OF THE DEVICE:

Welch Allyn FlexiPort Blood Pressure Cuffs product line consists of Reuse, Soft & Vinyl Blood Pressure Cuffs used for patient health screening assessment to determine the patient's systolic/diastolic blood pressure when used in conjunction with non-automated and automated sphygmomanometers. This product line was previously cleared under 510(k) premarket notification K070060 on December 18, 2007.

Welch Allyn FlexiPort Blood Pressure Cuffs are designed with the FlexiPort, a port connector which can rotate 360 degrees to reduce tube kinking and a standardized connector for quick exchange of tubing and fittings that interface with manual or electronic sphygmomanometers. The FlexiPort feature allows the interface tubing (either one- or two-tube) to remain with the blood pressure measurement device, while the cuff can be easily removed and moved from one location to another. The cuff can then be used universally within a facility on multiple devices.

The following are the types of FlexiPort Blood Pressure Cuffs available with the FlexiPort feature.

a. Welch Allyn FlexiPort Reusable Blood Pressure Cuffs (also referred as Reuse Blood Pressure Cuffs).
b. Welch Allyn FlexiPort Soft Blood Pressure Cuffs (also referred as Soft Blood Pressure Cuffs).

   Welch Allyn FlexiPort Vinyl Blood Pressure Cuffs (also referred as Vinyl Blood Pressure Cuffs).

INTENDED USE:

Welch Allyn FlexiPort Blood Pressure Cuffs are noninvasive blood pressure cuffs intended for use in conjunction with non-automated and automated sphygmomanometers to determine blood pressure in pediatric through adult patients.

FlexiPort Blood Pressure Cuffs are intended to be used by a clinically trained medical professional.

INDICATIONS FOR USE:

Welch Allyn FlexiPort Blood Pressure Cuffs are intended to be used for patient health screening assessment to determine patient's systolic/diastolic blood pressure when used in conjunction with non-automated and automated sphygmomanometers.

DEVICE COMPARISON TABLE

The device comparison Table 3 outlining the differences in the device features between the proposed device (subject to this premarket notification) and the device that was submitted under K070060.

Baxter

Table 3. Device Comparison and Substantial Equivalence

Characteristic	Predicate – FlexiPort Blood Pressure Cuff (K070060)	Proposed Device – FlexiPort Blood Pressure Cuffs	Discussion of Differences
Product code	DXQ	Same	N/A- No difference
Regulation Number	21 CFR 870.1120	Same	N/A- No difference
Intended Use	The FlexiPort Blood Pressure Cuff is used in conjunction with noninvasive blood pressure measurement systems. The cuff is nonsterile and is available in pediatric through adult sizes. The device is not intended for neonatal applications. The FlexiPort Blood Pressure Cuffs are not designed, sold, or intended for use, except as indicated.	Welch Allyn Blood Pressure cuffs are noninvasive blood pressure cuffs intended for use in conjunction with non-automated and automated sphygmomanometers to determine blood pressure in pediatric through adult patients.	The proposed device IFU does not constitute a new Intended Use from the predicate device as both the predicate and the proposed devices are intended for use to determine blood pressure in conjunction with blood pressure measurement systems. There is no change in the intended use or patient population. The elaboration simply provides greater clarity.
Intended Users	FlexiPort Blood Pressure Cuff is intended to be used by a clinically trained, medical professional.	Same	N/A- No differences
Indications for Use	The FlexiPort Blood Pressure Cuff is used in conjunction with noninvasive blood pressure measurement systems. The cuff is nonsterile and is available in pediatric through adult sizes. The device is not intended for neonatal applications. The FlexiPort Blood Pressure Cuffs are not designed, sold, or intended for use, except as indicated.	Welch Allyn FlexiPort Blood Pressure Cuffs are intended to be used for patient health screening assessment to determine patient's systolic/diastolic blood pressure when used in conjunction with non-automated and automated sphygmomanometers.	The proposed device's indications provide a more detailed description of indirect measurement of blood pressure. There is no change in the indications for use except minor rewording for clarity.

Baxter

Table 3. Device Comparison and Substantial Equivalence

Characteristic	Predicate – FlexiPort Blood Pressure Cuff (K070060)	Proposed Device – FlexiPort Blood Pressure Cuffs	Discussion of Differences
Contraindication	Welch Allyn FlexiPort Blood Pressure Cuffs are contraindicated for neonate use. Do not use on neonate patients.	Same	N/A- No difference.
Target Population	- The FlexiPort Blood Pressure Cuff is intended to be used on all patients, from Pediatric through adults, except for neonatal patients. - Compliant with AAMI and AHA sizing standards.	- Same target population. - Compliant with ANSI AAMI ISO 81060-1:2013 standard.	The proposed device has been tested to the latest and applicable AAMI ISO 81060-1:2013 standard, which now includes the AHA guidelines.
Sizes- arm circumference (Ranges in cm)	Small Infant (7-10) Infant (9-13) Small Child (12-16) Child (15-21) Small Adult (20-26) Adult (25-34) Adult Long (25-34) Large Adult (32-43) Large Adult Long (32-43) Thigh (40-55)	Small Infant (7-10) Infant (9-13) Small Child (12-16) Child (15-21) Small Adult (20-26) Adult (25-34) Adult Long (25-34) Large Adult (32-43) Large Adult Long (32-43) Thigh (40-55)	N/A- No difference.
Tube configuration	1 and 2 tube, interchangeable	Same	N/A- No difference.
Design/ Technology	**Reuse:** 1-piece cuff with integrated bladder. **Soft:** 1-piece cuff with integrated bladder.	Same	N/A- No difference.

Baxter

Table 3. Device Comparison and Substantial Equivalence

Characteristic	Predicate – FlexiPort Blood Pressure Cuff (K070060)	Proposed Device – FlexiPort Blood Pressure Cuffs	Discussion of Differences
	Vinyl: 1-piece cuff with integrated bladder.		
Human Factors	**Reuse, Soft & Vinyl:** -Latex free **Reuse:** - Cloth-like material, cleanable using hospital cleaners. **Soft & Vinyl:** - soft material or easy to clean vinyl. - color-coded sizes - rolled edge and rounded corners for patient comfort.	The FlexiPort Blood Pressure Cuffs have been found to be adequately designed for the intended users, uses, and use environments with applicable usability engineering principles (IEC 62366-1).	The proposed devices incorporate equivalent usability considerations to ensure patient comfort and ease of use. While the predicate describes specific design elements (soft material, round corners), the proposed device meets the same human factors goals through comprehensive usability engineering and risk analysis. The minor rewording does not impact function or safety. Both designs address comfort, usability, and safety for the same intended user population and environment.
Performance	Bench and laboratory tested to demonstrate conformance.	Same	N/A- No difference.
Materials	**Reuse:** Polyurethane coated nylon woven cloth Nylon hook and loop closure. **Soft & Vinyl:** PVC material with PVC & nylon hook and loop closure	**Reuse:** Polyether polyurethane film coated nylon woven cloth; Nylon laminated Polyurethane hook and loop closure. **Soft & Vinyl:** White spunlaced polyester nonwoven fabric; Nylon laminated with PVC hook and loop closure.	Changes have been made to the materials and material suppliers. Design control activities including risk assessment and verification have been conducted and confirmed that these changes do not impact the device's safety and effectiveness or performance.

Baxter

Table 3. Device Comparison and Substantial Equivalence

Characteristic	Predicate – FlexiPort Blood Pressure Cuff (K070060)	Proposed Device – FlexiPort Blood Pressure Cuffs	Discussion of Differences
Safety & Efficacy	- AAMI SP10, 2002: Requirements for Non-Automated Sphyg. (SP10 is revision-update of SP9). - AAMI/AHA bladder sizes - Biocompatibility: • ISO 10993-1	- ANSI AAMI ISO 81060-1:2013 Non-invasive sphygmomanometers Part 1: Requirements and test methods for non-automated measurement type. -Biocompatibility: • ISO 10993-1: 2018 • ISO 10993-5: 2014 • ISO 10993-10:2021 • ISO10993-23: 2021	The proposed device has been tested to the latest and applicable AAMI ISO 81060-1:2013 standard, which now includes the AHA guidelines. The proposed device has been tested to the latest and applicable Biocompatibility standards.
Sterility	Not supplied sterile.	Same	N/A - No difference.
Compatibility	Cuff can be used with 1 or 2 tube non-invasive blood pressure devices because of FlexiPort feature. Can be used with mechanical or electronic devices.	Same	N/A- No difference.
Packaging	**Reuse**: Each cuff packaged individually. **Soft & Vinyl**: Each cuff packaged individually and five cuffs grouped in a secondary polybag, and a total of 50 cuffs packaged in a shipping cardboard box.	**Reuse**: Each cuff packaged individually. Soft and Vinyl: Each cuff individually packaged in a polybag and 20 individually packaged cuffs are assembled in a corrugated shipping cardboard box.	The Soft and Vinyl predicate device contains different packaging configurations compared to the proposed device. The difference lies within the quantity of cuffs per shipping box and the removal of the intermediate five-unit bag. These differences are limited to external packaging configurations and do not affect the cuff's performance or labeling.

Baxter

Table 3. Device Comparison and Substantial Equivalence

Characteristic	Predicate – FlexiPort Blood Pressure Cuff (K070060)	Proposed Device – FlexiPort Blood Pressure Cuffs	Discussion of Differences
			Design control activities, including packaging integrity testing and handling validation and have confirmed that new packaging maintains product safety and is suitable for shipping, storage and clinical use.

SUMMARY OF DEVICE PERFORMANCE CONFIRMED BY BENCH TESTING

Non-Clinical testing of the proposed devices has been performed against requirements for performance, physical attributes, environmental conditions and safety, and to provide objective evidence that the device's intended use is met.

- Verification and validation demonstrated that design inputs were met. Verification involves testing requirements against pre-defined and approved protocols containing validated test methods and established acceptance criteria. All the testing met acceptance criteria.
- Cleaning and Disinfection validation was performed according to FDA Guidance *Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling* issued March 17, 2015.

The proposed devices were tested to evaluate their safety and effectiveness based on the standards and associated methods below:

- ISO 14971:2019 Medical Devices- Application of Risk Management to Medical Devices.
- ISO 15223-1: 2021 Medical Devices- Symbols to be Used with Medical Device Labels, Labeling and Information to be Supplied – Part 1: General Requirements.
- ANSI AAMI ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process.
- ANSI AAMI ISO 10993-5:2009/(R)2014 Biological evaluation of medical devices- Part5: Tests for invitro cytotoxicity.
- ISO 10993-10:2021 Biological evaluation of medical devices- Part 10: Tests for Skin sensitization.
- ISO 10993-23:2021 Biological evaluation of medical devices Part23: tests for irritation.
- ANSI AAMI ISO 81060-1:2007/(R)2013 Non-invasive sphygmomanometers Part-1: Requirements and test methods for non-automated measurement type.
- ANSI AAMI ISO 80369-1:2018 Small-bore connectors for liquids and gases in healthcare applications- Part 1: General requirements.
- ANSI AAMI ISO 80369-5:2016 Small-bore connectors for liquids and gases in healthcare applications- Part 5: Connectors for limb cuff inflation applications.

- ISTA 3A:2018 Packaged- Products for parcel delivery system shipment 70kg (150lb) or less.
- ANSI AAMI IEC 62366-1:2015+AMD1:2020 Medical devices – Medical devices Part 1: Application of usability engineering to medical devices, including Amendment 1
- ISO 81060-2:2018 Non-invasive sphygmomanometers Part 2: Clinical investigation of intermittent automated measurement type.

In addition to the above, several bench testing has been completed to confirm the device performs per its intended use. These include environmental tests (temperature and storage tests), mechanical strength tests (Tubing pull test, Change cycle life test and leak testing), durability tests (Inflation Cycles life test, Port cyclic rotation life test) and accuracy tests. The results of verification and validation demonstrate that the proposed devices have passed all established acceptance criteria and are as safe and effective as the predicate device for their intended use.

Substantial equivalence of the proposed device is demonstrated through performance testing, conformance to FDA recognized standards and comparison to the predicate device. The proposed devices, in comparison with the legally marketed predicate, has the same intended use, indications for use, environment for use, principle of operation, fundamental scientific technology, technical characteristics and functional outputs. Minor design or specification differences between the proposed devices and the predicate do not raise new questions related to safety or effectiveness. Based on the comparison analysis and test results, Baxter has concluded that the proposed devices to be substantially equivalent to the predicate device.

SUMMARY OF DEVICE PERFORMANCE CONFIRMED BY ANIMAL TESTING

Some animal testing will be performed during biocompatibility testing of the materials.

SUMMARY OF DEVICE PERFORMANCE CONFIRMED BY CLINICAL TESTING

No clinical tests are being performed to establish safety or effectiveness of the device

CONCLUSION:

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, Baxter Healthcare

concludes that this device, the Welch Allyn FlexiPort Blood Pressure Cuffs, have been appropriately designed for their intended use. The non-clinical data demonstrate that the proposed devices are as safe, effective and substantially equivalent to the predicate device that is currently marketed for the same intended use.