K070060
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5. *Premarket Notification [510(k)] Summary*

Date: January 3, 2007

Submitted By: Welch Allyn, Inc.
4341 State Street Road, P.O. Box 220
Skaneateles Falls, NY 13153-0220

DEC 1 8 2007

Phone: (315) 685-4571
Fax: (315) 685- 2532
Contact: John Sawyer
Vice President, Quality Assurance and Regulatory Affairs

Common Name: Blood Pressure Cuff

Trade Name: Welch Allyn FlexiPort™ Disposable Blood Pressure Cuff (One-Piece)
Welch Allyn FlexiPort™ Reusable Blood Pressure Cuff (One-Piece)

Classification Name: Cuff, Blood-Pressure

Classification: Class II per 21 CFR 870.1120

Predicate Devices: Critikon Soft Blood Pressure Cuff (K974080)
Sensa-Cuff, Models Infant, Child, Adult (K022482)

Description: FlexiPort™ Blood Pressure Cuffs are designed with the FlexiPort™, a standardized connector for quick exchange of tubing and fittings that interface with manual or electronic sphygmomanometers and inflation devices. This 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 to be used universally within a facility on multiple devices. The port connector can also rotate 360 degrees to reduce tube kinking.

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.

Performance: Bench and laboratory testing was conducted to demonstrate performance of the Welch Allyn FlexiPort™ Blood Pressure Cuff.

- Biocompatibility
- Compatibility with other devices
- Reprocessing
- Packaging

- Sterilizability
- Environmental
- Mechanical Strength
- Durability
- Accuracy

Subject Device and Predicate Device Comparison:

Subject Area	***Welch Allyn FlexiPort™***	***GE Sensa-Cuff***	***Critikon Soft Blood Pressure Cuff***
Indications For Use	Indirect measurement of blood pressure	Indirect measurement of blood pressure	Indirect measurement of blood pressure
Sizes – arm circumference (Ranges in cm)	Newborn (7-10) Infant (9-13) Small Child (12-16) Child (15-21) Small Adult (20-26) Adult (25-34) Large Adult (32-43) Thigh (40-55)	Infant (8-13) Child (12-19) Small Adult (17-25) Adult (23-33) Large Adult (31-40) Thigh (38-50)	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) Small Adult (17-25) Adult (23-33) Large Adult (31-40) Thigh (38-50)
Tube Configuration	1 and 2 tube, interchangeable	1 and 2 tube, built into specific cuff model number	1 and 2 tube, built into specific cuff model number
Safety & Efficacy	AAMI SP10, 2002 requirements for Non-Automated Sphyg. (SP10 is revision-update of SP9) ISO 10993-1 biocompatibility AAMI/AHA bladder sizes	AAMI SP9 requirements for Non-Automated Sphyg. ISO 10993-1, biocompatibility AAMI/AHA bladder sizes	Bench and laboratory tested to demonstrate conformance for biocompatibility, validation of reprocessing, and repeated inflations. AAMI/AHA bladder sizes
Sterility	Not supplied sterile. Capable of being sterilized using ETO.	Not supplied sterile.	Not supplied sterile.
Biocompatibility	Conforms to ISO 10993-1	Conforms to ISO 10993-1	Demonstrated performance for biocompatibility

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, Welch Allyn concludes that this device, the Welch Allyn FlexiPort™ Blood Pressure Cuff, is safe, effective and substantially equivalent to both the reusable GE Sensa-Cuff (K022482) and the disposable Critikon Soft Blood Pressure Cuff (K974080)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2007

Welch Allyn, Inc.
c/o Mr. John Sawyer
VP Quality Assurance and Regulatory Affairs
4341 State Street Road, Box 220
Skaneateles Falls, NY 13151-0220

Re: K070060
Trade/Device Name: FlexiPort Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: November 9, 2007
Received: November 13, 2007

Dear Mr. Sawyer:

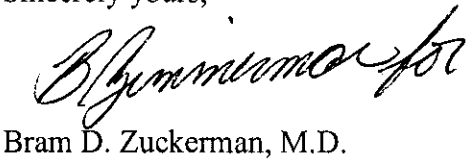
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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. 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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); good manufacturing practice requirements as set forth in the quality systems regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070060

Device Name: Welch Allyn FlexiPort™ Disposable Blood Pressure Cuff (One-Piece)
Welch Allyn FlexiPort™ Reusable Blood Pressure Cuff (One-Piece)

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.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070060