WelchAllyn

K122058

510(k) Summary

[As described in 21 CFR 807.92]

NOV 5 2012

Submitted by: Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, NY 13153-0220

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Date Prepared: October 22, 2012

Trade Name: Welch Allyn FlexiPort EcoCuff

Device Classification Name: Blood Pressure Cuff

Device Classification: Class II

Classification Reference: 870.1120

Classification Product Code: DXQ

Predicate Devices: Welch Allyn FlexiPort Blood Pressure Cuff
510(k) Number K070060

Indications for Use:

The FlexiPort EcoCuff Blood Pressure Cuff is intended to be used on the upper arm 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 EcoCuff blood pressure cuff is not designed, sold or intended for use, except as indicated.

This product is available for sale only upon the order of a physician or licensed health care professional.

Technological Characteristics:
The subject device has the same technological characteristics and indications for use as the predicate FlexiPort Blood Pressure Cuff. They both use the single port FlexiPort technology. They both are cuffs with an integrated bladder with a hook and loop closure system.
The subject device is made of polypropylene and has a slot feature in addition to the cuff range marker. The polypropylene is an economical material for use in a single patient use setting. The slot provides the clinician an additional means to correctly select the proper cuff size for the patient.

Non-Clinical Tests:
Bench top testing was conducted to ensure expected performance of the FlexiPort EcoCuff.

The following standards were applied to the FlexiPort EcoCuff.

Standard Identification Number	*Version*	*Title*
ISO 10993-1	2009	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process
AAMI / ANSI SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003	R2008	Manual, Electronic, or Automated Sphygmomanometers
ISTA 2A	2008	Packaged-Products 150 LB (68 KG) or Less
EN 1060-1	2009	Non-invasive Sphygmomanometers-Part 1 General Requirements
EN 1060-2	2009	Non-invasive Sphygmomanometers – Part 2: Supplementary Requirements for Mechanical Sphygmomanometers
ISO 14971	2007	Medical Devices – Application of Risk management to Medical Devices
ISO 81060-1	2007	Non Invasive Sphygmomanometers – Part 1: Requirements and Test Methods for Non-automated Measurement Type
ISO 81060-2	2009	Non Invasive Sphygmomanometers-Part 2: Clinical Validation of Automated Measurement Type
Guidance Document	1998	Non-Automated Sphygmomanometer (Blood Pressure Cuff) Guidance Version 1

Clinical Performance Data:

Not Applicable

Conclusion:

Based on the information presented in this 510(k) premarket notification, Welch Allyn's FlexiPort EcoCuff is determined to be substantially equivalent (as safe, as effective and performs as well as) to the currently marketed FlexiPort Blood Pressure Cuff.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

NOV 5 2012

Welch Allyn, Inc.
c/o Mr. Kevin Crossen
Director Regulatory Affairs
4341 State Street Road
P.O. Box 220
Skaneateles Falls, NY 13153-0220

Re: K122058
Trade/Device Names: Welch Allyn FlexiPort EcoCuff
Regulatory Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (Two)
Product Code: DXQ
Dated: October 22, 2012
Received: October 23, 2012

Dear Mr. Crossen:

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 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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): K122058

Device Name: Welch Allyn FlexiPort EcoCuff

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Prescription Use (Part 21 CFR 801 Subpart D) x 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 K122058