



Food and Drug Administration
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August 14, 2015

AccessClosure, Inc.
Kelly Jabbal
Manager, Regulatory Affairs
5452 Betsy Ross Drive
Santa Clara, California 95054

Re: K143613
Trade/Device Name: PaxWire Occlusion Balloon System
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: July 13, 2015
Received: July 14, 2015

Dear Kelly Jabbal,

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. 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); 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 contact the Division of Industry and Consumer Education 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>. 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

<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 Industry and Consumer Education 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,

Kenneth J. Cavanaugh -S

for

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)
K143613

Device Name
PaxWire Occlusion Balloon System

Indications for Use (Describe)

The PaxWire Occlusion Balloon System is indicated for temporary flow occlusion in the iliofemoral artery.

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.

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510(k) Summary
PaxWire™ Occlusion Balloon System

Submitter's Name and Address:

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Contact Name and Information:

Kelly Jabbal
Manager, Regulatory Affairs
Tel: 408-610-6517
Fax: 408-610-6702

Date Prepared:

August 13, 2015

Proprietary Name:

PaxWire™ Occlusion Balloon System ("PaxWire System")
Model No. ACX101

Common Name:

Vascular Clamp

Product Code:

MJN - Catheter, Intravascular Occluding, Temporary

Regulation Number:

21 CFR 870.4450

Predicate Device:

Primary:

Berenstein Occlusion Balloon Catheter (“Berenstein Catheter”)
Boston Scientific Corp.
K132990

Secondary:

Amplatz Super Stiff Guidewire (“Amplatz Guidewire”)
Meadox Medicals, a Division of Boston Scientific Corp.
K930622

Device Description:

The PaxWire™ Occlusion Balloon System (PaxWire System) is designed for use in the iliofemoral artery to provide temporary occlusion as well as a path for dilator and/or sheath introduction, removal or repositioning during catheterization procedures.

The PaxWire System consists of the following:

- An occlusion catheter (see **Figure 1** below) with a distal atraumatic stainless-steel J-tip (23 cm in length), a compliant Chronoprene balloon, an 80 cm working length stainless steel shaft with a maximum 0.035” diameter proximal to the balloon, and an internal valve on the proximal end of the catheter. The effective length of the PaxWire System is 99 cm with the inflation handle attached. The balloon can be inflated up to 12 mm for temporary flow occlusion in the iliofemoral artery (shown in un-inflated view in **Figure 1** below). The balloon includes radiopaque markers located at each end of the balloon to aid positioning during fluoroscopy. The internal valve can be manually opened to control balloon inflation.

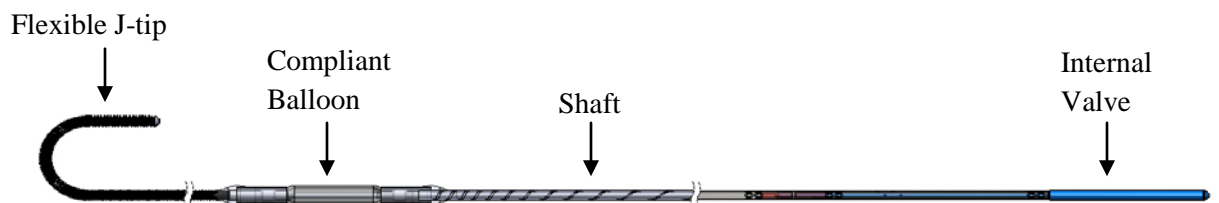


Figure 1. PaxWire Occlusion Balloon System (Catheter)

- An inflation handle that is manually operated and is used to inflate and deflate the balloon. The inflation handle can be removed while the balloon is inflated so that a dilator can be advanced over the proximal end of the device.
- A 10 cc Prep Syringe
- A 3 cc Inflation Syringe



Intended Use / Indications for Use:

The PaxWire System is indicated for temporary flow occlusion in the iliofemoral artery.

Comparison of Technological Characteristics:

The PaxWire System can be regarded as a “hybrid” of two predicate devices: the Berenstein Catheter and the Amplatz Guidewire. Both the PaxWire System and the Berenstein Catheter employ the same scientific concept of utilizing an internal lumen to inflate a distal compliant balloon to provide temporary occlusion. The Berenstein Catheter is placed over the guidewire, whereas the Paxwire System allows for placement independent of a guidewire. The PaxWire System also utilizes the same scientific concept of a wire feature of the Amplatz Guidewire to allow a sheath dilator to be advanced over the proximal end of the PaxWire System shaft. It is in this configuration that the PaxWire System is appropriately compared to the predicate devices.

Performance Data:

Performance data to support a determination of substantial equivalence included biocompatibility and bench testing as follows:

Biocompatibility Testing:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Hemolysis, direct contact using pooled blood from 3 donors
- Hemolysis, extract using pooled blood from 3 donors
- Systemic Toxicity
- Materials Mediated Pyrogenicity
- Partial Thromboplastin Time (PTT)
- Complement Activation
- Thromboresistance Test in Canine
- Bacterial Endotoxin



Bench Testing:

- Package Integrity
- Balloon Integrity
- Deflation Time
- Leak Test
- Weld Strength
- Inflated Balloon Pull and Torque
- Unconstrained Inflated Balloon Diameter and Burst
- Valve Remains Closed
- Force to Open/Close Valve and Maximum Force to Actuate the Valve
- Valve Tensile Strength and Cycling
- Extension Line to Stopcock and Inflation Handle Tensile Strength
- Lateral (Shaft) Stiffness
- Tip Flexibility
- Buckling
- Kinking
- Dimensional Verification of Crossing Profile, J-Tip Radius, Diameter and Effective Length
- Balloon Fatigue Cycling
- Corrosion
- Simulated Use

Conclusion:

The conclusions drawn from the testing outlined above demonstrate that the PaxWire System is substantially equivalent to the predicates.