April 24, 2019

QXMedical, LLC
Fernando Di Caprio
Chief Technology Officer
2820 Patton Road
Roseville, Minnesota 55113

Re: K183679
Trade/Device Name: Occlusion Balloon Catheter
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: MJN
Dated: March 20, 2019
Received: March 21, 2019

Dear Fernando Di Caprio:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183679

Device Name
Occlusion Balloon Catheter

Indications for Use *(Describe)*
The Occlusion Balloon Catheter is indicated for temporary occlusion of large vessels, including the superior vena cava, in applications including perioperative occlusion and emergency control of hemorrhage.

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.

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"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."

4 510(k) Summary

Date Prepared: April 24, 2019

Submitter Information:

Submitter's Name/Address	Contact Person
QXMédical, LLC 2820 Patton Road Roseville, MN 55113	Fernando Di Caprio Chief Technical Officer Phone: (651) 842-2053 Email: fernando.dicaprio@qxmedical.com

Device Information:

Device Classification Name	Catheter, Intravascular Occluding, Temporary
Common Name	Occlusion Balloon Catheter
Trade Name	Occlusion Balloon Catheter
Regulatory Class	Class II
Regulation Number	21 CFR 870.4450
Regulation Name	Vascular Clamp
Classification Product Code	MJN
510(k) Review Panel	Cardiovascular

Performance Standards:

No performance standards applicable to this product have been developed under Section 514 of the Act.

Predicate Device:

Predicate Device	Manufacturer	510(k) Status
Bridge Occlusion Balloon	Spectranetics, Inc.	K153530

Reference Device:

Reference Device	Manufacturer	510(k) Status
Stent Graft Balloon Catheter	QXMédical, LLC	K120381

Device Description:

The Occlusion Balloon Catheter is a multi-lumen catheter which has a compliant polyurethane balloon with a maximum diameter of 32mm at 60cc inflation volume. The balloon has a nominal length of 80mm. The device is constructed with a blended PEBA shaft and is available in two models; one model is compatible with 8Fr (or larger) introducer sheaths and one model is compatible with 10Fr (or larger) introducer sheaths. Both models provide the same balloon performance with respect to sizing and occlusion. The two models are intended for individual physician preference for patient-specific sheath selection. The device has an effective length of 90cm and is compatible with 0.035" diameter guidewires. Three (3) platinum-iridium radiopaque marker bands are placed on the shaft to facilitate balloon placement in the anatomy prior to inflation. The proximal end of the catheter has an integral PEBA bifurcation manifold with female luer ports to allow communication with the balloon inflation lumen and guidewire lumen. A PVC extension tube (with stopcock) is connected to the balloon inflation port to facilitate handling. The device is a single use, sterile device. The device models are outlined in the table below:

Device Models			
Description	**Introducer Sheath Compatibility**	**Balloon Diameter**	**Shaft Length**
Occlusion Balloon Catheter – 8 Fr	≥ 8 Fr	18 – 32 mm	90 cm
Occlusion Balloon Catheter – 10 Fr	≥ 10 Fr	18 – 32 mm	90 cm

Intended Use/Indications for Use:

The Occlusion Balloon Catheter is indicated for temporary occlusion of large vessels, including the superior vena cava, in applications including perioperative occlusion and emergency control of hemorrhage.

Summary of Non-Clinical Testing:

The Occlusion Balloon Catheter underwent mechanical, performance, and biocompatibility assessments to support a determination of substantial equivalence. These tests provide reasonable assurance that the device meets the established performance criteria and will perform as intended. The testing did not raise any new questions of safety and effectiveness.

The mechanical and performance tests performed on the Occlusion Balloon Catheter include:

Tests Performed	
Visual inspections	Vessel occlusion
Dimensional inspections	Balloon fatigue
Freedom from leakage	Kink resistance and radius
Luer syringe compatibility	Burst or leak volume
Guidewire compatibility	Freedom from fragmentation
Introducer sheath compatibility	Tensile strength (hub to shaft)
Balloon compliance (volume v. diameter)	Tensile strength (tip to shaft)
Inflation and Deflation time	Tensile strength (extension tube)
Balloon inflation characteristics	Torque strength
Radiopacity	Shelf life testing
Corrosion resistance	Package integrity
Shipping/distribution testing	Environment conditioning

Clinical Testing

Clinical evaluation was not required for this device.

Comparison to Predicate and Reference Devices

The Occlusion Balloon Catheter has the same or similar intended use, indications, technological characteristics, and principles of operation as the previously cleared predicate device. Like the predicate device, the Occlusion Balloon Catheter is placed into the patient's vascular system via percutaneous access. It achieves temporary occlusion of large vessels by inflating a compliant balloon on the distal end of a multi-lumen shaft with a known quantity of inflation fluid using a standard syringe. Like the predicate device, the Occlusion Balloon Catheter has a maximum inflation volume of 60 ml and sterilized using ethylene oxide (EO).

Additionally, the Occlusion Balloon Catheter has the same materials, technological characteristics, manufacturing methods and principles of operation as the previously cleared reference device. The Occlusion Balloon Catheter has all the same materials (shaft, balloon, tip, manifold, and packaging) and manufacturing methods as the reference device. Like the reference device, the Occlusion Balloon Catheter is placed into the patient's vascular system via percutaneous access. It achieves temporary occlusion of large vessels by inflating a compliant balloon on the distal end of a multi-lumen shaft with a known quantity of inflation fluid using a standard syringe. Like the reference device, the Occlusion Balloon Catheter has a maximum inflation volume of 60 ml and sterilized using ethylene oxide (EO).

No significant differences impacting safety and effectiveness were identified with respect to intended use, materials, technological characteristics, and principles of operation.

Substantial Equivalence Comparison

Based on a comparison of the intended use/indications for use, principle of use, intended anatomical location, and technological characteristics, along with the results from a series of non-clinical tests, the Occlusion Balloon Catheter has been shown to be substantially equivalent to the predicate device.

The Occlusion Balloon Catheter raises no new questions of safety or effectiveness compared to the predicate device and is eligible for premarket clearance.

Conclusion

Based on the successful results from the Non-Clinical Testing performed and the Substantial Equivalence Comparison, we conclude that the device is substantially equivalent to the legally marketed predicate device listed above.