K120381

5 510(k) Summary

FEB 24 2012

Date Prepared: December 30, 2011

Submitter Information:

Submitter's Name/Address	Contact Person
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Device Information:

Trade Name	Q50® PLUS Stent Graft Balloon Catheter
Common Name	Catheter, Percutaneous
Classification Name	Catheter, Percutaneous
Product Code	DQY, MJN
Regulation	Class II, 21 CFR 870.1250
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
Stent Graft Balloon Catheter	Via Biomedical, Inc.	K091624

Device Description:

The QXMédical Stent Graft Balloon Catheter is a multi-lumen catheter which has a compliant polyurethane balloon with a maximum diameter of 50mm at 60cc inflation volume. The device is constructed with an 8Fr diameter blended PEBA shaft and is available in two usable lengths, 65 cm and 100 cm. The device is compatible with 12Fr (or larger) introducer sheaths and 0.038" diameter (or smaller) guidewires. Two platinum-iridium radiopaque marker bands are placed within the balloon to facilitate balloon placement 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	**Balloon Diameter**	**Shaft Length**	**Model Number**
Q50® PLUS (65cm)	10mm-50mm	65cm	**Q50-65P**
Q50® PLUS (100cm)	10mm-50mm	100cm	**Q50-100P**

Intended Use/Indications for Use:

The Stent Graft Balloon Catheter is intended for temporary occlusion of large vessels, or to expand vascular prostheses.

Summary of Non-Clinical Testing:

The QXMédical Stent Graft Balloon Catheter underwent mechanical, performance, and biocompatibility assessments to verify that the device functions in a safe and effective manner.

The mechanical tests performed on the QXMédical Stent Graft Balloon Catheter include:

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)
Deflation time	Tensile strength (extension tube)
Balloon inflation characteristics	Torque strength
Radiopacity	Shelf life testing
Corrosion resistance	Package integrity
Shipping/distribution testing	Environment conditioning

All tests met specifications. These results provide assurance that the device has been designed and evaluated to assure conformance to the requirements for its indications for use.

Substantial Equivalence Comparison

The QXMédical Stent Graft Balloon Catheter is substantially equivalent to the predicate device based on a comparison of the indications for use and the technological characteristics. The following table provides a comparison of the technological characteristics of the QXMédical Stent Graft Balloon Catheter and the predicate device:

	QXMédical Stent Graft Balloon Catheter	*Predicate Device* Via Biomedical Stent Graft Balloon Catheter (K091624)
Shaft Configuration	0.105" diameter, 3 – lumen, 65cm & 100cm effective lengths, *PEBA*	0.105" diameter, 3 – lumen, 65cm & 100cm effective lengths, *PEBA*
Tip	Tapered, *Polyurethane*	Tapered, *Polyurethane*
Balloon	10mm to 50mm range, 50mm (60cc) max. *Polyurethane*	10mm to 50mm range, 50mm (60cc) max. *Polyurethane*
Radiopaque Markers	Two markers, 40mm spacing, *Pt - Ir*	Two markers, 40mm spacing, *Pt - Ir*
Manifold	Bifurcation style, with female luer connections to guidewire lumen & inflation lumen *PEBA*	Bifurcation style, with female luer connections to guidewire lumen & inflation lumen *PEBA*
Strain Relief	Heat shrunk, *Polyolefin*	Heat shrunk, *Polyolefin*
Extension Tube	Single-lumen, *PVC, DEHP-free*	Single-lumen, *PVC, DEHP-free*
Stopcock Style	One-Way, *Polycarbonate & acetal*	Three-Way, *Polycarbonate & polyethylene*
Minimum Sheath	12 Fr	12 Fr
Maximum Guidewire	0.038"	0.038"
Vessel Occlusion	Up to 41mm	Up to 41mm
Balloon Inflations	Maximum of 20 cycles	Maximum of 20 cycles
Packaging Configuration	Double sterile barrier	Double sterile barrier
Sterilization	Ethylene Oxide	Ethylene Oxide

One difference between the QXMédical Stent Graft Balloon Catheter and the predicate device is the style of stopcock attached to extension tube (inflation port). The QXMédical Stent Graft Balloon Catheter has a 1-Way stopcock while the predicate device has a 3-way stopcock. These stopcocks have different designs, materials and methods of operation; however, both styles are well characterized and familiar to users. This difference does not raise any issues of safety or effectiveness.

The testing performed confirms that the QXMédical Stent Graft Balloon Catheter will perform as intended.

Conclusion

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

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

FEB 24 2012

QXMedical, LLC
c/o Mark Job
Responsible Third Party Official
Regulatory Technical Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K120381
Trade/Device Name: Q50 PLUS Stent Graft Balloon Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, MJN
Dated: February 6, 2012
Received: February 7, 2012

Dear Mr. Job:

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 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,

M. A. Hillebenne

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 Statement

510(k) Number (if known): K120381

Device Name: **Q50® PLUS Stent Graft Balloon Catheter**

Indications for Use:

The Stent Graft Balloon Catheter is intended for temporary occlusion of large vessels, or to expand vascular prostheses.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. G. Hillebenne

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K120381