DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2016

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

Re: K160561
Trade/Device Name: Boosting Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: September 30, 2016
Received: October 3, 2016

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. 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,

Brian D. Pullin -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160561

Device Name
Boosting Catheter

Indications for Use *(Describe)*
The Boosting Catheter is intended for use in conjunction with guiding catheters or sheaths during coronary and peripheral interventional procedures to guide and support interventional devices, including guidewires, traverse discrete portions of the vasculature, allow for interventional device exchanges and provide a conduit for infusion of saline solution, diagnostic contrast agents and therapeutic agents.

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 - K160561

Date Prepared: October 27, 2016

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 Trade Name	Boosting Catheter™
Device Common Name	Guiding Catheter
Device Classification Name	Catheter, Percutaneous (per 21 CFR 870.1250)
Classification Product Code	DQY
Regulatory Classification	Class II (per 21 CFR 870.1250)
Review Panel	Cardiovascular

Performance Standards:

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

Predicate Devices:

Predicate Device	510(k) Status
Access and Support Catheter	K123311
Concierge Guiding Catheter	K132409

Reference Devices:

Reference Device	510(k) Status
Guidezilla Catheter	K123765
CrossBoss Catheter	K091841

Device Description:

The Boosting Catheter is an over-the-wire percutaneous catheter with an atraumatic tip. The catheter has an effective length of 150cm and available in four (4) diameter models; each compatible with various guiding catheters or sheaths as shown in the following table:

Catalog Number	Model Number	Catheter I.D.	Catheter O.D.	Compatible Guiding Catheter	Compatible Sheath
BC52-150	9005-001	0.052”	0.064”	6 Fr (0.066” MIN ID)	5 Fr (0.066” MIN ID)
BC57-150	9005-002	0.057”	0.068”	6 Fr (0.070” MIN ID)	5.5 Fr (0.072” MIN ID)
BC63-150	9005-003	0.063”	0.076”	7 Fr (0.078” MIN ID)	6 Fr (0.079” MIN ID)
BC72-150	9005-004	0.072”	0.086”	8 Fr (0.088” MIN ID)	7 Fr (0.092” MIN ID)

The Boosting Catheter is constructed with a proximal manipulation shaft connected to a distal tube or guiding catheter segment. The manipulation shaft is used to advance the distal tube segment over a guidewire and through a guiding catheter (or sheath) to a desired location in the coronary or peripheral vasculature. Once positioned, diagnostic or interventional devices (including guidewires) may be delivered or exchanged though the guiding catheter and the Boosting Catheter distal tube segment. Further, procedural fluids (such as saline, contrast agents or therapeutic agents) can be delivered through the guiding catheter and the distal tube segment to a desired location in the coronary or peripheral vasculature. The distal tube segment has two (2) radiopaque markers to facilitate fluoroscopic guidance and a lubricious outer coating to assist with catheter advancement. The manipulation shaft has a molded handle and strain relief to assist with handling. The strain relief is printed with the catheter dimensional information. The device is supplied sterile and intended for single use only.

Intended Use/Indications for Use:

The Boosting Catheter is intended for use in conjunction with guiding catheters or sheaths during coronary and peripheral interventional procedures to guide and support interventional devices, including guidewires, traverse discrete portions of the vasculature, allow for interventional device exchanges and provide a conduit for infusion of saline solution, diagnostic contrast agents and therapeutic agents.

Comparison of Technological Characteristics with the Predicate Devices:

The Boosting Catheter has similar intended use as the predicate devices along with similar principle of use, body contact duration (< 24 h) and intended anatomical location (coronary and peripheral vasculature). Additionally, the Boosting Catheter and the predicate devices are technologically similar with regards to the following characteristics:

- Construction, including over-the-wire configuration
- Materials
- Design and manufacturing techniques
- Hydrophilic coating
- Radiopaque tip
- Dimensions (ID, OD, overall length)
- Guidewire, sheath and guiding catheter compatibility
- Packaging
- Sterilization

The differences between the Boosting Catheter and the predicate devices are:

- Guidewire lumen configuration and length
- Addition of some materials common to other cardiovascular catheters

The test data presented in this submission demonstrate substantial equivalence of the Boosting Catheter.

Summary of Non-Clinical Testing:

The Boosting 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 mechanical and performance tests performed on the Boosting Catheter included:

Mechanical and Performance Test Summary	
Visual inspections	Torque strength
Dimensional evaluations	Tensile strength
Device compatibility	Simulated use
Guiding catheter/sheath compatibility	Coating adherence
Device support	Particulate evaluation
Catheter stiffness & flexibility	Fluoroscopic visualization

Mechanical and Performance Test Summary	
Device retraction & insertion	Fluid delivery
Catheter fatigue	Shelf life testing
Catheter kink resistance	Package integrity
Corrosion resistance	Shipping/distribution testing
	Environmental conditioning

The biocompatibility tests performed on the Boosting Catheter included:

Biocompatibility Test Summary	
Cytotoxicity	Hemolysis
Sensitization	Immunology (complement activation)
Irritation / Intracutaneous reactivity	*In Vivo* Thromboresistance
Systemic toxicity (acute)	Pyrogenicity (material mediated)
Genotoxicity	Physicochemical tests

Clinical Testing

Clinical evaluation was not required for this device.

Substantial Equivalence Comparison Summary

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 Boosting Catheter has been shown to be substantially equivalent to the predicate devices.