May 14, 2020

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

Re: K200317
Trade/Device Name: Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: April 15, 2020
Received: April 16, 2020

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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 Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K200317

Device Name
Support Catheter

Indications for Use *(Describe)*
The support catheter is intended for use during coronary and peripheral interventional procedures to guide and support guidewires, traverse discrete portions of the vasculature, allow for guidewire 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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# 510(k) Summary QXMédical Support Catheter (K200317)

**Date Prepared: May 14, 2020**

**Submitter Information:**

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

**Device Information:**

| | |
|---|---|
| **Device Classification Name** | Catheter, Percutaneous |
| **Common Name** | Support Catheter |
| **Trade Name** | Support Catheter |
| **Regulatory Class** | Class 2 |
| **Regulation Number** | 21 CFR 870.1250 |
| **Regulation Name** | Percutaneous Catheter |
| **Classification Product Code** | DQY |
| **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 | 510(k) Status |
|---|---|
| Access and Support Catheter | K123311 |

**Device Description:**

The subject Support Catheter is an over-the-wire (OTW) single-lumen catheter with a tapered atraumatic tip. The catheter is available in fifteen (15) size models compatible with standard 0.014", 0.018" and 0.035" diameter guidewires and with effective lengths of 65 cm, 90 cm, 135 cm, 150 cm and 180 cm. The distal end of the catheter incorporates three (3) distal radiopaque markers to assist with fluoroscopic guidance and estimating distances. A hydrophilic coating on the distal end assists with catheter advancement. The proximal end of the catheter has a molded manifold with a female luer connection in fluid communication with the catheter lumen. The catheter lumen is used for guidewire passage and exchanges as well as fluid infusion. The catheter guidewire size and length are printed on the strain relief. The device is supplied sterile and intended for single use only.

**Intended Use/Indications for Use:**

The Support Catheter is a single-lumen catheter designed for use in the vascular system and intended for use during coronary and peripheral interventional procedures to guide and support guidewires, traverse discrete portions of the vasculature, allow for guidewire exchanges and provide a conduit for infusion of saline solution, diagnostic contrast agents and therapeutic agents.

**Summary of Non-Clinical Testing:**

The subject Support 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 Support Catheter include:

| **Tests Performed** | |
|---|---|
| Visual/Dimensional inspections | Catheter stiffness & flexibility |
| Freedom from leakage | Kink resistance and radius |
| Luer syringe compatibility | Guidewire support |
| Guidewire compatibility | Catheter fatigue |
| Sheath compatibility | Tensile strength |
| Guiding catheter compatibility | Markerband retention |
| Simulated use | Particulate evaluations |
| Coating integrity | Torque strength |
| Fluoroscopic visualization | Burst pressure |
| Corrosion resistance | Shelf life testing |
| Fluid flow rates | Package integrity |
| Shipping/distribution testing | Environment conditioning |

## Clinical Testing

Clinical evaluation was not required for this device.

## Comparison to Predicate Device

The subject Support 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 subject Support Catheter is a single lumen catheter with a tapered distal tip and three (3) radiopaque markers to assist with fluoroscopic guidance. The catheters have a hydrophilic coating on the distal end to aid with tracking, access and passage. They are available in various sizes (diameters & lengths) to accommodate different guidewires and allow access to various anatomical locations. Like the predicate device, the subject Support Catheter is placed into the patient's vascular system via percutaneous access. The catheters are threaded over a guidewire and through a guiding catheter (or sheath) to access discrete portions of the patient's vasculature. Once the desired placement is achieved, the catheters may provide support for further advancement of the guidewire. Additionally, the guidewire may be removed and exchanged for another guidewire or the guidewire may be removed to allow infusion of saline, contrast or other procedural solutions. Like the predicate device, the subject Support Catheter is a single-use device and sterilized using ethylene oxide (EO).

Minor differences between the subject Support Catheter and the previously cleared predicate device are outlined in the following table:

| **Technological Characteristics** | ***Subject Device:*** **Support Catheter** | ***Predicate Device:*** **Access and Support Catheter** | **Notes** |
|---|---|---|---|
| **Catheter Effective Lengths** | 65cm, 90cm, 135cm, 150cm and 180cm | 65cm, 90cm, 135cm and 150cm | Subject device includes 180cm length models |
| **Catheter Tip Design** | Distal tip is 1.25mm long and tapered | Distal tip is 2.0mm long and tapered | Subject device has a shorter tip |
| **Hydrophilic Coating Length** | 40cm coating length on *65cm* and *90cm models.*<br>80cm coating length on *135cm, 150cm* and *180cm models.* | 40cm coating length on *all models.* | The *135cm, 150cm* and *180cm* effective length models of the subject device have 80cm coated length |

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 subject Support Catheter has been shown to be substantially equivalent to the predicate device.

The subject Support 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 as safe and effective as the legally marketed predicate device listed above.