DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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June 16, 2017

Wilson-Cook Medical, Inc.
Tiffanny A. Thomas
Global Regulatory Affairs Specialist
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K171223
Trade/Device Name: Quantum TTC Biliary Balloon Dilator
Regulation Number: 21 CFR 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: FGE
Dated: April 25, 2017
Received: April 26, 2017

Dear Tiffanny A. Thomas:

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,

Joyce M. Whang -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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)*
K171223

Device Name
Quantum TTC Biliary Balloon Dilator

Indications for Use *(Describe)*
The Quantum TTC Biliary Balloon Dilator is used to dilate strictures of the biliary tree.

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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510(k) SUMMARY

Name: Tiffanny A. Thomas, Global Regulatory Affairs Specialist
Address: Wilson-Cook Medical, Inc.
4900 Bethania Station Road,
Winston-Salem NC 27105

Phone: 336-744-0157
Date: 4/25/2017

Trade Name: Quantum TTC Biliary Balloon Dilator
Common/Usual Name: Balloon Dilator

Classification Name: Biliary Catheter and Accessories
21 CFR 876.5010, FGE Class II

Predicate Device: Quantum T.T.C Balloon Dilation Catheter K935094, 01/24/1995

Reference Device: Wilson-Cook Biliary Dilation Balloon K040800 06/25/2004

Intended Use
The Quantum TTC Biliary Balloon Dilator is used to dilate strictures of the biliary tree.

Device Description:
The subject balloon dilator is a 3 cm polyethylene terephthalate (PET) balloon mounted at the distal end of pebax catheter. The balloon can be inflated to single size diameters of 4, 6, 8, or 10 mm. The catheter is available in lengths of 180 cm or 320 cm with a 6.8-5.5 Fr diameter.

Product Number	Working Length	Balloon Diameter
QBD-10x3-E	320 cm	10 mm
QBD-10X3	180 cm	10 mm
QBD-8X3-E	320 cm	8 mm
QBD-8X3	180 cm	8 mm
QBD-6X3-E	320 cm	6 mm
QBD-6X3	180 cm	6 mm
QBD-4X3	180 cm	4 mm

Substantial Equivalence:
Minor design changes were made to the predicate Quantum T.T.C Balloon Dilation Catheter cleared to market via K935094. These changes include: a narrowing of the intended use, catheter length, catheter diameter, catheter material, the addition of a 10 mm diameter balloon and non-patient contacting radiopaque (RO) band markers. The subject device also includes an inflation extension line and wire guide extension line with a strain relief at molded juncture. The subject dilation balloon is equivalent to the predicate device with respect to intended use, technological characteristics, and materials.

Performance Data:
A Risk Analysis was completed to assess the impact of modifications made to the cleared device using the Design Failure Modes, Effects and Criticality Analysis (DFMECA) method.

Design verification and validation testing was performed as a result of the risk analysis assessment. Results from design validation and/or verification testing provide reasonable assurance that the modifications to the device do not raise any new questions of safety or effectiveness.

Summary of non-clinical testing:
The following non-clinical testing was conducted to demonstrate the performance of the subject device and confirmed that the subject device performs as intended.

- Balloon Diameter and Length
- Distensibility
- Balloon Burst Strength
- Tensile Testing of the Device Joint Components
- Radiopacity Testing
- Dimensional Testing Through Simulated Use
- Shelf Life Testing
- Packaging Validation

Biocompatibility testing was performed in accordance with the FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process" and per ISO 10993-1:2009, *Biological evaluation of medical devices- Evaluation and testing within risk management process.*

Conclusions:
We believe that the subject device is substantially equivalent to the predicate device in terms of intended use, key operating principles, materials and technological characteristics. We consider the risks associated with the modifications to the subject device to have been adequately addressed through our Design Control Processes and do not affect safety or effectiveness of the device.