July 6, 2018

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

Re: K173659
Trade/Device Name: Howell D.A.S.H Extraction Balloon With Multiple Sizing
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary Catheter and Accessories
Regulatory Class: II
Product Code: GCA
Dated: June 7, 2018
Received: June 11, 2018

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.

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,

Glenn B. Bell -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)*

K173659

Device Name
Howell D.A.S.H Extraction Balloon With Multiple Sizing

Indications for Use *(Describe)*
This device is used for endoscopic removal of biliary stones and for contrast injection.

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: 11/2/2017

Name of Device:
Trade Name: Howell D.A.S.H Extraction Balloon with Multiple Sizing
Common/Usual Name: Extraction Balloon

Classification Name: Biliary Catheter and Accessories

21 CFR 876.5010, GCA, Class II

Predicate Device: Tri-Ex Extraction Balloon with Multiple Sizing, K170292, 09/20/2017

Intended Use
This device is used for endoscopic removal of biliary stones and for contrast injection.

Device Description:
The subject extraction balloon is comprised of a latex balloon mounted at the distal end of a nylon catheter with three internal lumens. On the proximal end of the device, there is a blue handle with three ports that lead to the three internal lumens. On one side of the handle there is a leur lock injection port. In the center of the handle is the wire guide lumen port that is capped with a clear adapter. This clear adapter allows for contrast injection while the wire guide is in place. The remaining port is used for balloon inflation with a stopcock to control air movement in and out of the balloon.

The balloon can be inflated to three sizes, 8.5 mm, 12 mm and 15 mm diameters. Radiopaque bands placed at the distal and proximal ends of the balloon provide fluoroscopic visualization of the balloon location. The catheter has a working length of 190cm. There are ink markings on the catheter for endoscopic visualization.

Substantial Equivalence:
Minor design changes were made to the predicate Tri-Ex Extraction Balloon with Multiple Sizing. These changes on the subject device include a reduced catheter length and diameter, along with new additional ink markings on the catheter. The subject extraction balloon is equivalent to the predicate device with respect to intended use, technological characteristics, and materials of construction.

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 verification testing provide reasonable assurance that the modifications to the device do not raise any new questions of safety or effectiveness.

Summary on Non-Clinical Testing:
The following performance testing was conducted to demonstrate the basic performance of the subject device and confirmed that the subject device performs as intended.

- Functional Testing
- Balloon Inflation
- Distal Ink Marking Validation
- Shelf Life Testing
- Packaging Validation

The subject extraction balloon developed utilizing our internal Design Control procedures as required by 21 CFR § 820.30. Design Control Procedures are inclusive of the following elements:

- Design Planning
- Risk Analysis
- Design Input
- Design Output
- Design Review
- Design Verification
- Design Validation
- Process Validation
- DFMECA/ PFMECA
- Design Changes
- Design Transfer

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 believe the risks associated with the modifications to the subject device have been adequately addressed through our Design Control Processes and do not affect safety or effectiveness of the device.