May 24, 2018

Wilson-Cook Medical, Inc. / Cook Endoscopy
Theresa De Prat
Global Regulatory Affairs Specialist
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K172665
Trade/Device Name: Classic Cotton Cannulatome®
CannulaTome II® Double Lumen Sphincterotome
Cotton CannulaTome II® PC
UTS® Ultra Taper Sphincterotome
Tri-Tome pc® Triple Lumen Sphincterotome
Howell D.A.S.H.® Sphincterotome with DomeTip®
Billroth II Sphincterotome
Soehendra® BII Sphincterotome
Models ACU-1 and ACU-1-VL active cords
Regulation Number: 21 CFR§ 876.4300
Regulation Name: Endoscopic Electrosurgical Unit and Accessories
Regulatory Class: II
Product Code: KNS
Dated: April 23, 2018
Received: April 24, 2018

Dear Theresa De Prat:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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)*
K172665

Device Name
Classic Cotton Cannulatome®, CannulaTome II® Double Lumen Sphincterotome, Cotton CannulaTome II® PC, UTS® Ultra Taper Sphincterotome, Tri-Tome pc® Triple Lumen Sphincterotome, Howell D.A.S.H.® Sphincterotome with DomeTip®, Billroth II Sphincterotome, Soehendra® BII Sphincterotome, and Models ACU-1 and ACU-1-VL active cords

Indications for Use *(Describe)*

Howell D.A.S.H.® Sphincterotome with DomeTip® (Cook Reference Part Numbers DASH-21, DASH-21-480, DASH-1, DASH-260, DASH-480, DASH-ACRO-25-450, DASH-35, DASH-ACRO-35-260, DASH-35-480, DASH-ACRO-35-450): This device is used for cannulation of the ductal system and for sphincterotomy. If preloaded, also aids in bridging difficult strictures during ERCP.

Tri-Tome pc® Triple Lumen Sphincterotome (Cook Reference Part Numbers TRI-20, TRI-20M, TRI-25, TRI-25M, TRI-25M-P, TRI-25M-SLT, TRI-30, TRI-30M): This device is used for cannulation of the ductal system and for sphincterotomy.

Classic Cotton® CannulaTome® (Cook Reference Part Numbers CCPT-25, CCPT-25-MONO, CCPT-25ME), CannulaTome II® Double Lumen Sphincterotome (Cook Reference Part Numbers CT-20, CT-20M, CT-30, CT-30M), Cotton Cannulatome II® PreCurved Double Lumen Sphincterotome (Cook Reference Part Numbers CT-25, CT-25M, CT-25M-P UTS®), and Ultra Taper Sphincterotome (Cook Reference Part Numbers UTS-15, UTS-20, UTS-20M, UTS-25, UTS-25M, UTS-30, UTS-30M): This device is used for cannulation of the ductal system and for sphincterotomy.

Billroth II Sphincterotome (Cook Reference Part Numbers PTG-20-6-BII-NG) and Soehendra® BII Sphincterotome (Cook Reference Part Numbers PT-5.5-BII-SOEHENDRA): This device is used for the cannulation of the ductal system and for sphincterotomy.

Models ACU-1 and ACU-1-VL active cords: This device is used to connect Cook monopolar electrosurgical accessories to compatible electrosurgical generators.

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

Sphincterotomes and Active Cords
Traditional 510(k) Premarket Notification

April 23, 2018

Applicant Information

Applicant:	Wilson-Cook Medical, Inc. /Cook Endoscopy 4900 Bethania Station Road Winston-Salem, North Carolina 27105
Contact:	Theresa de Prat, Regulatory Affairs Specialist II
Phone:	(336) 744-0157 ext. 396518
Fax:	(336) 201-5994

Device Information

Trade Names:	Classic Cotton Cannulatome® CannulaTome II® Double Lumen Sphincterotome Cotton CannulaTome II® PC UTS® Ultra Taper Sphincterotome Tri-Tome pc® Triple Lumen Sphincterotome Howell D.A.S.H.® Sphincterotome with DomeTip® Billroth II Sphincterotome Soehendra® BII Sphincterotome Models ACU-1 and ACU-1-VL active cords
Common Names:	Papillotome, sphincterotome, active cord
Regulation Name:	Endoscopic electrosurgical unit and accessories
Regulation Number:	21 CFR 876.4300
Product Code:	KNS
Device Class:	Class II
Review Panel:	Gastroenterology-Urology

Predicate Device

Name:	Zimmon® Papillotome
510(k) Number:	K901443
Date:	Cleared June 18, 1990

Device Description

The sphincterotomes described in this submission are a sterile, single use devices compatible with the accessory channel of endoscope. The device consists of a long, thin plastic tube (cannula) with a wire running the length of its interior. A small portion of

that wire is exposed at its distal end. The roof of the papilla is opened by passing high-frequency current through the wire, exposing the biliary or pancreatic orifices for selective cannulation. The active cords are accessories to sphincterotomes so that a sphincterotome can be connected to an electrosurgical unit.

Intended Use

Howell D.A.S.H.® Sphincterotome with DomeTip® (Cook Reference Part Numbers DASH-21, DASH-21-480, DASH-1, DASH-260, DASH-480, DASH-ACRO-25-450, DASH-35, DASH-ACRO-35-260, DASH-35-480, DASHACRO-35-450): This device is used for cannulation of the ductal system and for sphincterotomy. If preloaded, also aids in bridging difficult strictures during ERCP.

Tri-Tome pc® Triple Lumen Sphincterotome (Cook Reference Part Numbers TRI-20, TRI-20M, TRI-25, TRI-25M, TRI-25M-P, TRI-25M-SLT, TRI-30, TRI-30M): This device is used for cannulation of the ductal system and for sphincterotomy.

Classic Cotton® CannulaTome® (Cook Reference Part Numbers CCPT-25, CCPT-25-MONO, CCPT-25ME), CannulaTome II® Double Lumen Sphincterotome (Cook Reference Part Numbers CT-20, CT-20M, CT-30, CT-30M), Cotton Cannulatome II® PreCurved Double Lumen Sphincterotome (Cook Reference Part Numbers CT-25, CT-25M, CT-25M-P UTS®), and Ultra Taper Sphincterotome (Cook Reference Part Numbers UTS-15, UTS-20, UTS-20M, UTS-25, UTS-25M, UTS-30, UTS-30M): This device is used for cannulation of the ductal system and for sphincterotomy.

Billroth II Sphincterotome (Cook Reference Part Numbers PTG-20-6-BII-NG) and Soehendra® BII Sphincterotome (Cook Reference Part Numbers PT-5.5-BII-SOEHENDRA): This device is used for the cannulation of the ductal system and for sphincterotomy.

Models ACU-1 and ACU-1-VL active cords: This device is used to connect Cook monopolar electrosurgical accessories to compatible electrosurgical generators.

Comparison to Predicate Device

The subject device and predicate device have the same intended use and different technological characteristics.

Substantial Equivalence Comparison

Characteristic	Zimmon® Papillotome (K901443)	Cook Sphincterotomes and Active Cords (K172665)
Intended Use	Used for endoscopic papillotomy/sphincterotomy.	This device is used for cannulation of the ductal system and for sphincterotomy. If preloaded, also aids in bridging difficult strictures during ERCP.
Sterile/Non-Sterile	Sterile, EO	Same
Disposable/Reusable	Disposable	Same
Cutting Wire Length	15-30 mm	15-30 mm
Cutting Wire Diameter	0.012″ (braided)	0.012″ (braided) 0.0075-0.010″ (monofilament)
Handle configuration	Three Ring Handle	Same
Tip configuration	Straight or Tapered	Tapered or DomeTip
Wire Guide / Injection Port Extension	No	Yes
Wire Control Port (WCP) with Slide	No	Yes (on TriTome pc® Select)
Cutting Wire Material	304 Stainless Steel	303 stainless steel or 304 stainless steel; Parylene C added for “Protector” versions
Ink Marker Material	Gem Black	Black, Green, Blue, Silver, Copper/Bronze, Gold
Packaging	PTEG Tray with Tyvek Lid	Tyvek and Mylar pouch
Catheter Design	Single lumen	Single, double or triple lumen
Catheter Design/Material	Polytetrafluoroethylene (PTFE)	Same
Catheter Length	200 cm	196 or 200 cm
Catheter Diameter	5 Fr	4-7 Fr
Wire Guide Compatibility	Not applicable	0.021-0.035″

None of the differences in technological characteristics raise different questions of safety and effectiveness. Furthermore, performance data from acceptable scientific testing methods provide evidence that the subject device is substantially equivalent to the predicate device.

Performance Data

Performance testing consisting of sterilization, shelf life, biocompatibility, and non-clinical bench testing, as follows, demonstrate that the subject device meets the performance requirements to fulfill the intended use of the device.

- GLP Cytotoxicity 1X MEM ISO elution
- GLP ISO Intracutaneous irritation – 2 extracts
- GLP ISO Guinea Pig Maximization, – 2 extracts
- IEC 60601-1: 2006 + A12: 2014 (3.1 edition)- Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-2: 2017 (6.0 edition) - Medical Electrical Equipment - Part 2-2: Particular Requirements For The Basic Safety And Essential Performance Of High Frequency Surgical Equipment And High Frequency Surgical Accessories
- IEC 60601-2-18: 2009 (3.0 edition) - Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- Ink visualization
- Visualization of Cutting Wire
- Orientation of Cutting Wire
- Fluoroscopic Visibility
- Drive Wire to Handle Joint Strength
- Brass Insert to Handle Joint Strength
- Active Cord to Pin Detachment
- Force to Bow
- Functional Age Testing
- Sterile Barrier and Functional Testing After Shipping
- Active Cord: Wire to Universal Insert Solder Joint Strength
- Active Cord: Wire to Banana Plug Solder Joint Strength
- Active Cord: Wire to Valley Lab Plug Solder Joint Strength
- Active Cord: Functional Testing at Time Zero
- Active Cord: Functional Testing after Shipping
- Sterilization validation
- ETO residual testing
- Packaging visual inspection
- Burst testing
- Dye leak testing