February 1, 2019

Wilson-Cook Medical, Inc.
℅ Daniel Dillon
Senior Regulatory Scientist
MED Institute
1330 Win Hentschel Boulevard
West Lafayette, Indiana 47906

Re: K182319/S001
Trade/Device Name: Glo-Tip® Spray Catheter
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: OCX
Dated: January 24, 2019
Received: January 24, 2019

Dear Daniel Dillon:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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,

Daniel G. Walter Jr -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K182319

Device Name
Glo-Tip® Spray Catheter

Indications for Use *(Describe)*
The Glo-Tip® Spray Catheter is used in conjunction with an endoscope to spray the gastrointestinal mucosa.

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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001. 510(k) Summary

Glo-Tip® Spray Catheter

Traditional 510(k) Premarket Notification

October 1, 2018

Applicant Information

Applicant:	Wilson-Cook Medical, Inc. /Cook Endoscopy 4900 Bethania Station Road Winston-Salem, North Carolina 27105
Contact:	Paula Joyce, Vice President, Regulatory Affairs\Corporate Compliance Officer
Phone:	(336) 744-0157 ext. 396245
Fax:	(336) 201-5994

Device Information

Trade Name:	Glo-Tip® Spray Catheter
Common Names:	Spray catheter
Classification Name:	Endoscope and accessories
Regulation Number:	21 CFR 876.1500
Product Code:	OCX
Device Class:	Class II
Review Panel:	Gastroenterology-Urology

Predicate Device

Name:	Hobbs Mistifier Medical Endoscopic Spray Catheter
510(k) Number:	K030765
Date:	Cleared June 9, 2003

Device Description

The Glo-Tip® Spray Catheter (subject device) is a sterile, single use device compatible with the accessory channel of an endoscope. The device consists of a long, thin polytetrafluoroethylene (PTFE) tube (catheter) with a stylet (metal wire) that together are introduced into the ductal area or elsewhere in the GI tract. Fluid (e.g., water or saline) can be injected through the catheter to spray the tissue that needs cleaning. The Glo-Tip®

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Spray Catheter can also be used in chromoendoscopy (to apply a dye to the mucosa of the gastrointestinal tract through an endoscope to aid in disease detection).

Indications for Use

The Glo-Tip® Spray Catheter is used in conjunction with an endoscope to spray the gastrointestinal mucosa.

Comparison to Predicate Device

The subject device and predicate device have the same intended use and different technological characteristics, as follows:

Characteristic	**Hobbs Mistifier Medical Endoscopic Spray Catheter (K030765)**	**Glo-Tip® Spray Catheter (Subject of This 510(k))**
Intended Use	Used as a flexible endoscopic accessory to apply legally marketed solutions for washing or staining mucosal tissue.	Used in conjunction with an endoscope to spray the gastrointestinal mucosa.
Design		
Catheter working length	165 cm or 260 cm	235 cm
Catheter diameter	2.6 mm	6.9 Fr (2.3 mm)
Compatible scope channel	Unknown	2.8 mm
Spray tip	Forward-facing, 360°	Same
Materials		
Catheter	PTFE	PTFE
Proximal-fitting	Unknown	Polycarbonate
Radiopaque crimping band	Unknown	Tantalum
Spray tip	"Metal"	303 Stainless Steel and Brass
Packaging	Unknown	Tyvek/Mylar Pouch
Other		
Injection Port?	Yes	Same
Sterile?	Yes	Same
Single Use?	Yes	Same

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

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Performance Data

Performance testing consisting of sterilization, shelf life, biocompatibility, and non-clinical bench testing demonstrates that the Glo-Tip® Spray Catheter meets the performance requirements to fulfill the intended use of the device.

Sterilization validation demonstrates that the device has a sterility assurance level of 10^{-6} with acceptable sterilization residuals. Biocompatibility testing is summarized as follows:

Test method	Results
ISO 1X MEM Elution Method	Test article considered not cytotoxic.
ISO Intracutaneous Irritation Study in Rabbits: two extracts	Test article considered a non-irritant.
ISO Guinea Pig Maximization: two extracts	Test article considered not a sensitizer.

Shelf-life and non-clinical bench testing is summarized as follows:

Requirement	Acceptance Criteria (summary)	Results
Packaging shall maintain functional integrity of the device following EO sterilization and shipping.	Meet user requirements and have acceptable visual appearance following two sterilization cycles and simulated shipping conditions.	Packages met acceptance criteria.
Product must perform intended use over labeled shelf life.	Same requirements as above, except *following two sterilization cycles and aging.*	Product performed as intended over labeled shelf life
Sterile product must be adequately packaged to maintain sterile barrier during expected shipping conditions.	Non-opened sterile packaging shall not show any signs of functional damage, such as holes in the pouch and/or voids in the seal area after simulated shipping conditions.	No signs of functional damage.
Package maintains sterile barrier over labeled shelf life.	Same requirements as above previous, except *following aging.*	Package has acceptable sterile barrier.
Device must be a Glo-tip device.	Distal tip of device must be fluoroscopically visible.	Tip is fluoroscopically visible.

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Requirement	Acceptance Criteria (summary)	Results
The product label shall contain accurate dimensional/ compatibility information	Catheter outer diameter: 6.9 Fr with acceptable tolerance.	Device dimensions are in accordance with labeling.
	Working length: 235 with acceptable tolerance.	
In accordance with ISO 8600-1:2013, Clause 4.3: The maximum insertion portion width shall not be larger than that stated in the instruction manual	Maximum insertion portion width ≤2.6 mm when measured in accordance with ISO 8600-4: 2014, using a measuring instrument with a minimum accuracy of 0.05 mm	