July 26, 2018

Cook Incorporated
James O. Ebot Enaw, M.D., MS
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47402

Re: K181712
Trade/Device Name: San Antonio Stopcock
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: ODC
Dated: June 27, 2018
Received: June 28, 2018

Dear James O. Ebot Enaw:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181712

Device Name
San Antonio Stopcock

Indications for Use *(Describe)*
This device is intended to regulate flow through the working channel of a ureteroscope, cystoscope, or other endoscope.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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510(k) Summary

San Antonio Stopcock
As required by 21 CFR §807.92
Date Prepared: July 09, 2018

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	James O. Ebot Enaw
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 339-2235 x105648
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	San Antonio Stopcock
Common Name:	Endoscope Channel Accessory
Classification Name:	Endoscope and Accessories
Classification Regulation:	21 CFR §876.1500, Product Code ODC
Device Class/Classification Panel:	Class II, Gastroenterology/Urology

Predicate Device:

The predicate device is the Endoscopic Cap, Check-Flo® Adapter, Side-Arm Adapter, Tuohy-Borst Adapter cleared on March 22, 2018, under 510(k) K173105.

Device Description:

The San Antonio Stopcock is a one-way stopcock with a male luer lock adapter (MLLA) and a barbed fitting. The device is comprised of a polycarbonate body, a nylon barbed adapter, and a polyethylene valve stem. The polycarbonate stopcock body has a MLLA and a female luer adapter (FMLA). The nylon barbed fitting has a MLLA that is attached to the FMLA of the stopcock body. The polyethylene valve stem assembly is seated within the polycarbonate stopcock body and controls the flow of liquids. The San Antonio Stopcock is operated by fitting the male luer end to the female connection of the endoscope and the barbed end to an irrigation set or other tubing. The device is sold sterile and is intended for one-time use.

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Indications for Use:

This device is intended to regulate flow through the working channel of a ureteroscope, cystoscope, or other endoscope.

Comparison to Predicate Device:

The proposed device has similar indications for use, methods of operation, and fundamental technological characteristics to the One-Way Stopcock component of the Check-Flo® Adapter included in the predicate device. Differences between the proposed device and the predicate device include minor differences in indications for use, design, and material. Characteristics of the subject device that differ from the One-Way Stopcock component of the Check-Flo® Adapter included in the predicate device are supported by testing and analysis.

Technological Characteristics:

Performance and biocompatibility testing was conducted in accordance with applicable standards to confirm the reliable performance of device characteristics. The following tests have been conducted on the San Antonio Stopcock, subject of this submission, to ensure reliable design and performance under the specified design requirements:

- Compatibility and Leakage Testing – Testing demonstrated that the San Antonio Stopcock met the compatibility requirements with supporting devices and that the device does not leak under a gravity flow test setup.
- Biocompatibility Testing – Per ISO 10993-1 and FDA guidance, testing for Cytotoxicity, Sensitization, and Intracutaneous Reactivity demonstrated that the devices are biocompatible.

For these tests, all pre-determined acceptance criteria were met.

Conclusion:

The results of these tests provide reasonable assurance that the San Antonio Stopcock will function as intended. The available evidence demonstrates that the subject devices are substantially equivalent to the predicate device, the Endoscopic Cap, Check-Flo® Adapter, Side-Arm Adapter, Tuohy-Borst Adapter cleared on March 22, 2018 (K173105). The minor differences between the subject and predicate devices also do not raise new questions of safety and/or effectiveness. The data provided support a determination of substantial equivalence to the predicate device.