March 22, 2018

Cook Incorporated
Samuel Engelman
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K173105
Trade/Device Name: Endoscopic Cap, Check-Flo® Adapter, Side-Arm Adapter, Tuohy-Borst Adapter
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: ODC
Dated: February 20, 2018
Received: February 21, 2018

Dear Samuel Engelman:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173105

Device Name
Endoscopic Cap, Check-Flo® Adapter, Side-Arm Adapter, Tuohy-Borst Adapter

Indications for Use *(Describe)*
This device is intended to resist the backflow of fluid around an instrument inserted 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.

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2.0 510(k) Summary

Endoscopic Cap, Side-Arm Adapter, Check-Flo Adapter, and Tuohy-Borst Adapter
21 CFR §807.92
Date Prepared: September 28, 2017

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Samuel Engelman
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 339-2235 x104340
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	Endoscopic Cap Check-Flo® Adapter Side-Arm Adapter Tuohy-Borst Adapter
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:

- Primary predicate device: OBP Self Sealing Endoscopic Seal (K091838).
- Secondary predicate device: Gateway™ Advantage Y-Adapter (K130909)

Device Description:

The Endoscopic Cap covers female Luer locks and bulb-type endoscopic fittings. The Endoscopic Cap is constructed from silicone. The proximal end is manufactured in three ways: without a hole, with a small hole, and with a large hole. The small hole is compatible with instruments that are 0.025 – 0.038 inches in diameter. The large hole is compatible with devices that are 7.0-12.0 Fr.

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The Check-Flo Adapters have a linear, cylindrical shape and attach to female Luer locks and bulb-type endoscopic fittings. The Check-Flo Adapter is constructed from four components: male Luer lock, body, valve, and cap. The distal side of the Check-Flo Adapter is an acetal male Luer lock. The body is constructed from acetal and connects all the components. The valve is a silicone disc and is seated in the cap. The cap is constructed from acetal and is located at the distal end of the Check-Flo Adapter. The Check-Flo Adapters are compatible with devices that are less than or equal to 9.0 Fr.

The Check-Flo Adapter design has two variations: a side-arm assembly and universal tubing. The side-arm assembly is a 10 cm length of vinyl tubing with a female Luer lock made from polycarbonate. The side-arm assembly comes with an additional one-way or three-way stopcock constructed from polycarbonate and polyethylene. The Check-Flo Adapter with universal tubing includes a segment of white silicone tubing. It protrudes 2.5 cm from the distal end of the male Luer lock and is 4.0 French in diameter.

The Side-Arm Adapter is shaped like the letter “y” and attaches to female Luer locks. It is constructed from four components: the body, male Luer lock, o-ring, and cap. The body is constructed from acetal. The protruding side-arm of the body has a female Luer lock. A one-way stopcock is provided and is constructed from polycarbonate and polyethylene. The male Luer lock is constructed from acetal and is located on the distal end of the body. The o-ring is seated inside the cap located on the proximal end of the body. The Side-Arm Adapter is compatible with instruments that are 3.0 - 6.0 Fr.

The Tuohy-Borst Adapter has a linear, cylindrical shape and attaches to female Luer locks. The Tuohy-Borst Adapter is constructed from four components: tightening knob, body, sealing ring, and rotator. The tightening knob is located on the proximal side of the Tuohy-Borst Adapter. The body is constructed from polycarbonate and connects all the components. The sealing ring is seated inside the rotator located on the distal end of the body. The Touhy-Borst is compatible with instruments that are 6.0 Fr and smaller.

The Tuohy-Borst has an alternate design where the body has an additional side-arm with female Luer lock. This design has the same four basic components.

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Indications for Use:

This device is intended to resist the backflow of fluid around an instrument inserted through the working channel of a ureteroscope, cystoscope, or other endoscope.

Comparison to Predicate Device:

The subject devices have similar indications for use, methods of operation, and fundamental technological characteristics as the predicate devices. Differences between the subject devices and the predicate devices include a difference in product code, indications for use, components, design, and material. Characteristics of the subject devices that differ from the predicate devices are supported by testing and analysis.

Performance Data:

The following testing was performed in order to demonstrate that the proposed Endoscopic Cap, Side-Arm Adapter, Check-Flo Adapter, and Tuohy-Borst Adapter met applicable design and performance requirements.

- Biocompatibility
- Sterilization
- Leakage
- Device Compatibility and Integrity
- Flow Rate
- Accelerated Age

Conclusion:

The results of these tests support a conclusion that the Endoscopic Cap, Side-Arm Adapter, Check-Flo Adapter, and Tuohy-Borst Adapter will perform as intended. The subject devices do not raise new questions of safety or effectiveness as compared to the predicate devices.