DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 28, 2017

Cook Incorporated
Rebecca Odulio (Li-Chun Liu)
Regulatory Affairs Specialist
750 Daniels Way, P.O. Box 489
Bloomington, IN 47402

Re: K171602
Trade/Device Name: Williams Cystoscopic Injection Needle
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FBK
Dated: May 31, 2017
Received: June 1, 2017

Dear Rebecca Odulio (Li-Chun Liu):

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Charles Viviano -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)*

K171602

Device Name

Williams Cystoscopic Injection Needle

Indications for Use *(Describe)*

The Williams Cystoscopic Injection Needle is used for cystoscopic injection into the urethra, bladder neck, and bladder wall.

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

Williams Cystoscopic Injection Needle

21 CFR §807.92

Date Prepared: May 31, 2017

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Contact:	Rebecca Odulio (Li-chun Liu)
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Contact Phone:	(812) 339-2235 x104673
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	Williams Cystoscopic Injection Needle
Common Name:	Endoscopic Injection Needle, Gastroenterology-Urology
Classification Name:	Endoscope and Accessories
Classification Regulation:	21 CFR §876.1500, Product Code FBK
Device Class/Classification Panel:	Class II, Gastroenterology/Urology

Predicate Device:

Cook Injection Needles (Cook Urological Inc., K022484) is the predicate device for the Williams Cystoscopic Injection Needle.

Device Description:

The Williams Cystoscopic Injection Needle is a semi-rigid injection needle. It is provided in 3.7 or 5.0 French sizes with 35 or 45 centimeters long polyurethane catheter, which ends with a 7 or 8 millimeter length stainless steel beveled tip cannula that is available in 20 to 25 needle gages. The subject device is sterilized with EtO and is intended for one-time use.

Indications for Use:

The Williams Cystoscopic Injection Needle is used for cystoscopic injection into the urethra, bladder neck, and bladder wall.

Comparison to Predicate Device:

The Williams Cystoscopic Injection Needle has similar methods of operation, materials, and fundamental technological characteristics as the predicate device. Differences between the subject device and the predicate device include minor dimensional variations that fall within the range of the predicate device and an additional feature of a grip wing hub. Characteristics of the subject device that differ from the predicate device are supported by testing to demonstrate that the subject device met the design input requirements for the instruction for use. The change for which this device is submitted is the more specific indications for use.

	Indications for Use
Predicate device	To deliver a variety of injectable material into tissues during laparoscopic, hysteroscopy, cystoscopic, endoscopic, transurethral procedures and open surgical procedures. The type of material to be injected will be dependent on the nature of the procedure, but such materials may include for example, saline, contrast media, collagen, silicone, Teflon, local anesthetics, etc.
Subject device	Used for cystoscopic injection into the urethra, bladder neck, and bladder wall.

Performance Data:

The following testing were performed to demonstrate that the subject Williams Cystoscopic Injection Needle met applicable design and performance requirements and support a determination of substantial equivalence. Where applicable, testing was done per applicable ISO international standards.

- Biocompatibility – Biological risks have been evaluated in accordance with ISO 10993-1 and FDA's Guidance on ISO 10993-1 and determined to be acceptable for the intended uses of the subject devices.
- Shelf Life – A three-year shelf life is supported by device performance testing after accelerated aging to the equivalence of three years. All predetermined acceptance criteria were met.
- Functional Verification – Testing demonstrated that the subject device functions as intended. The results showed that acceptance criteria were met.
- Dimension Verification – Testing demonstrated that the subject device functions as intended. The results showed that acceptance criteria were met.

Conclusion:

The results of these tests provide reasonable assurance that the subject Williams Cystoscopic Injection Needle functions as intended and does not raise new questions of safety or effectiveness as compared to the predicate device.

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- Functional Verification – Testing demonstrated that the subject device functions as intended. The results showed that acceptance criteria were met.
- Dimension Verification – Testing demonstrated that the subject device functions as intended. The results showed that acceptance criteria were met.

Conclusion:

The results of these tests provide reasonable assurance that the subject Williams Cystoscopic Injection Needle functions as intended and does not raise new questions of safety or effectiveness as compared to the predicate device.