June 26, 2019

Cook Incorporated
Irasema Rivera
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47404

Re: K191485
Trade/Device Name: Deflectable Brush Biopsy Set
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDX
Dated: June 3, 2019
Received: June 4, 2019

Dear Irasema Rivera:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Glenn B. Bell, Ph.D.
Assistant Division Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*

K191485

Device Name
Deflectable Brush Biopsy Set

Indications for Use *(Describe)*

The Brush Biopsy Sets are intended to obtain pathology specimens from lesions in the ureter, renal pelvis, infundibula or calyces under direct vision.

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

Deflectable Brush Biopsy Set
21 CFR §876.1500
Date Prepared: June 3, 2019

Submitted By:

Submission:	Traditional 510(k) Premarket Notification
Applicant:	Cook Incorporated
Primary Contact:	Irasema Rivera
Secondary Contact:	Paul Meyer
Applicant Address:	Cook Incorporated 750 Daniels Way Bloomington, IN 47404
Primary Contact Phone:	(812) 335-3575 x105166
Secondary Contact Phone:	(812) 335-3575 x105299
Contact Fax:	(812) 332-0281

Device Information:

Trade Name:	**Deflectable Brush Biopsy Set**
Common Name:	Endoscopic Cytology Brush
Classification Name:	Endoscope and accessories
Classification Regulation:	21 CFR §876.1500, Product Code FDX
Device Class/Classification Panel:	Class II, Gastroenterology/Urology

Predicate Devices:

- Primary predicate device: Vance Deflectable Biopsy Brush Set (K810372)
- Secondary predicate device: Urological Biopsy Brush Set (K770913)

Reference Devices:

- Brush Biopsy Sets and Deflectable Brush Biopsy Set (K182231)

Device Description:

The Deflectable Brush Biopsy Set is designed to be used through rigid or flexible endoscopes in order to obtain pathology specimens from lesions in the ureter, renal pelvis, infundibula, or calyces under direct vision. The Deflectable Brush Biopsy Set consists of a stainless steel shaft, radiopaque polytetrafluoroethylene

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catheter, and a nylon brush at the distal tip. The Deflectable Brush Biopsy Set is 3.2 French with a length of 115 centimeters. The Deflectable Brush Biopsy Set has a 3-ring handle at the proximal end that allows for deflection of the brush tip to within 15° from the shaft. The stainless steel shaft of the brush assembly is straight for the length of the catheter, and protrudes 6 centimeters from the distal tip of the catheter.

The sets will be supplied sterile and are intended for one-time use. The sets are packaged in a tray with lid in a peel-open pouch with a three-year shelf life.

The Deflectable Brush Biopsy Set subject of this submission have the same intended use, materials, dimensions, sterilization method, and shelf life as the Cook devices subject of reference submission Brush Biopsy Sets and Deflectable Brush Biopsy Set (K182231).

Indications for Use:

The Brush Biopsy Sets are intended to obtain pathology specimens from lesions in the ureter, renal pelvis, infundibula or calyces under direct vision.

Comparison to Predicate Devices:

The Deflectable Brush Biopsy Set is substantially equivalent to the predicate devices, Vance Deflectable Biopsy Brush Set (K810372), and Urological Biopsy Brush Set (K770913) in that the devices have the same intended uses and fundamental technological characteristics and are similar in design, dimensions, and materials of construction.

The differences from the predicate Vance Deflectable Brush Biopsy Set (K810372) include:

- Indications for Use
- Catheter sizes
- Packaging, sterilization method, and shelf life

The differences from the predicate Urological Biopsy Brush Set (K770913) include:

- Indications for Use
- Catheter material
- Catheter sizes
- Packaging sterilization method and shelf life

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Characteristics of the subject device set that differ from the predicate devise are supported by testing analysis.

Performance Data:

The following testing was performed in order to demonstrate that the subject Deflectable Brush Biopsy Set met applicable design and performance requirements:

- Biocompatibility
- Dimensional Verification of the Catheter
- Bristle Integrity
- Corrosion Following Exposure to Artificial Urine
- Tensile Strength
    - Catheter Shaft
    - Wire Shaft to Distal Tip
    - Handle-to-Wire Shaft
- Sterilization
- Packaging/Distribution
- Shelf Life/Stability

Conclusion:

The results of these tests support a conclusion that the Deflectable Brush Biopsy Set will perform as intended. The subject device does not raise new questions of safety or effectiveness as compared to the predicate devices. Therefore, the data provided in this submission support a determination of substantial equivalence.