May 1, 2019

Cook Incorporated
Chelsea Woods
Regulatory Affairs Specialist
750 Daniels Way
Bloomington, IN 47402

Re: K182231
Trade/Device Name: Brush Biopsy Set and Deflectable Brush Biopsy Set
Regulation Number: 21 CFR § 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: FDX
Dated: March 25, 2019
Received: March 26, 2019

Dear Chelsea Woods:

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,

Mark R. Kreitz -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
Indications for Use

510(k) Number (if known)
K182231

Device Name
Brush Biopsy Set and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Brush Biopsy Set
and
Deflectable Brush Biopsy Set
21 CFR §876.1500
Date Prepared: April 25, 2019

Submitted By:
Submission: Traditional 510(k) Premarket Notification
Applicant: Cook Incorporated
Primary Contact: Chelsea Woods
Secondary Contact: Andrew Breidenbach
Applicant Address: Cook Incorporated
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Bloomington, IN 47404
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Secondary Contact Phone: (812) 339-2235 x105147
Contact Fax: (812) 332-0281

Device Information:
Trade Name: Brush Biopsy Set and 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)

Device Description:
The Brush Biopsy Set and Deflectable Brush Biopsy Set are 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 Brush Biopsy Set consists of a stainless steel shaft, a catheter, and a nylon brush at the distal tip. The Brush Biopsy Set is available in two sizes: 3.2 French with a length of 115 centimeters, or 5 French with a length of 67 centimeters. The 3.2 French version has a stainless steel wire
shaft, a catheter constructed of radiopaque polytetrafluoroethylene, and a connector cap and pin vise located at the proximal end. The 5 French version has a stainless steel coil shaft, a catheter constructed of vinyl radiopaque tubing, and a side-arm adapter attached to the proximal end.

The Deflectable Brush Biopsy Set consists of a stainless steel shaft, a radiopaque vinyl catheter, and a nylon brush at the distal tip. The Deflectable Brush Biopsy Set is 5 French with a length of 67 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 7 centimeters from the distal tip of the catheter on the 5 French Deflectable Brush Biopsy Set to allow for deflection.

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

**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 Brush Biopsy Set and Deflectable Brush Biopsy Set are 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 Biopsy Brush Set (K810372) include:

- Indications for Use
- Catheter sizes
- Packaging, sterilization method, and shelf life (not stated in predicate 510(k)s)

The differences from the predicate Urological Biopsy Brush Set (K770913) include:
• Indications for Use
• Catheter material
• Catheter sizes
• Proximal fitting on 5 Fr Brush Biopsy Set
• Packaging, sterilization method, and shelf life (not stated in predicate 510(k)s)

Characteristics of the subject device sets 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 subject Brush Biopsy Set and Deflectable Brush Biopsy Set met applicable design and performance requirements:

• Biocompatibility
• Dimensional Verification of the Catheter
• Simulated Use and Bristle Integrity
• Corrosion Following Exposure to Artificial Urine
• Tensile Strength
  • Catheter Shaft
  • Wire Shaft to Distal Tip
  • Proximal Wire Shaft
• Sterilization
• Packaging/Distribution
• Shelf Life/Stability
• Acute Performance in a Porcine Urinary Model

Conclusion:

The results of these tests support a conclusion that the Brush Biopsy Set and Deflectable Brush Biopsy Set will perform as intended. The subject devices do 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.