March 29, 2023

Bibbinstruments AB
℅ John Smith
Partner
Hogan & Lovells US LPP
555 13th St. NW
Washington, DC 20004

Re: K212423
Trade/Device Name: EndoDrill® Model X
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: FCG
Dated: February 24, 2023
Received: February 24, 2023

Dear John Smith:

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212423

Device Name
EndoDrill® Model X biopsy instrument

Indications for Use *(Describe)*
The EndoDrill® Model X is intended to be used with an ultrasound endoscope for ultrasonically guided fine needle sampling of submucosal- and extramural lesions within gastrointestinal tract (i.e. esophagus, mediastinal masses, stomach, pancreas, liver, small- and large intestines, lymph nodes and perirectal masses). This device is for diagnostic purposes only.

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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510(K) SUMMARY

DATE

March 24, 2023

SUBMITTER

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CONTACT PERSON

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DEVICE NAME

Classification Name	Biopsy Instrument
Trade/Common Name	EndoDrill® Model X biopsy instrument
Classification	Class II
Product Code	FCG
Regulation Number	21CFR876. 1075

PREDICATE/REFERENCE DEVICES:

Olympus EZ Shot 3 Plus 19G, Single Use Aspiration Needle, K180449

Boston Scientific Radial Jaw™ 4 Single-Use Hot Biopsy Forceps, K101657

INDICATIONS FOR USE:

The EndoDrill® Model X is intended to be used with an ultrasound endoscope for ultrasonically guided fine needle sampling of submucosal- and extramural lesions within gastrointestinal tract (i.e. esophagus, mediastinal masses, stomach, pancreas, liver, small- and large intestines, lymph nodes and perirectal masses). This device is for diagnostic purposes only.

DEVICE DESCRIPTION:

EndoDrill® Model X

The EndoDrill® Model X biopsy instrument consists of a single-use handle with a flexible sheath and a cylinder tip that can be rotated to collect tissue samples. An outer sheath covers the tip to facilitate smooth insertion, positioning of the instrument and extraction. The hollow cylinder allows for multiple samples being taken continuously without removing the instrument for harvesting between biopsies. Rotation is facilitated by an isolated reusable electrical motor controlled by the user. No current, heat, smoke or sparks are introduced into the patient.

The device is designed to be used in flexible endoscopic instruments with ultrasound (EUS) used for examinations of the gastrointestinal tract.
The single-use biopsy instrument consists of a needle and handle that are supplied sterile and is for single patient use only. The needle contains all patient contact pathways and is fully disposable. Cleaning, re-processing and/or re- sterilization of the instrument is prohibited. The needle is inserted through the working channel of a flexible endoscope and fixed at the endoscope handle. The single-use needle and handle consists of the following pre-assembled, sterile components:

1. A biopsy needle consisting of stainless-steel with a coring cylinder tip collecting samples in a fluid- and airtight tubing when rotated.
2. An outer sheath that surrounds the rotating needle and may be used to place the inner needle at the biopsy site.
3. A handle that is mounted to the working channel of an endoscope, used to control sampling and attaches to a reusable drive cable that mechanically transfers rotation.

The reusable electrical motor and drive cable facilitating the rotation of the tip are supplied non-sterile and reusable. The motor unit contains an on/off safety switch and rotation is activated with a pedal attached to the motor. The drive cable that mechanically transmits rotation to the needle is mounted on the handle prior to sampling. The motor unit accommodates a DC motor which includes a power indicator light and attachments for power cable, drive cable and pedal. The motor is isolated and provides mechanical rotation to the single-use handle via the drive cable. No current, heat, smoke or sparks are introduced into the patient.

The device description is complete, and no figures of the device are present.

TECHNOLOGICAL CHARACTERISTIC AND SUBSTANTIAL EQUIVALENCE:

The following table provides more detailed information regarding the basis for the determination of substantial equivalence:

Parameter	Boston Scientific Single-Use Hot Biopsy Forceps (Predicate)	EndoDrill® Model X (510k applicant)	Olympus EZ Shot 3 Plus (Reference)
Indications for use	These single-use biopsy forceps are specifically designed to collect tissue endoscopically for histologic examination. These forceps should not be used for any other purpose than the intended function. These Single-Use Hot Biopsy Forceps are intended to be used through an endoscope to cauterize and remove polyps and/or tissue specimens throughout the alimentary tract. The alimentary tract includes the esophagus, stomach, duodenum, jejunum, ileum and colon.	The EndoDrill® Model X is intended to be used with an ultrasound endoscope for ultrasonically guided fine needle sampling of submucosal- and extramural lesions within gastrointestinal tract (i.e. esophagus, mediastinal masses, stomach, pancreas, liver, small- and large intestines, lymph nodes and perirectal masses). This device is for diagnostic purposes only	This instrument has been designed to be used with an Olympus ultrasound endoscope for ultrasonically guided fine needle aspiration (FNA) and fine needle biopsy (FNB) of submucosal and extramural lesions within the gastrointestinal tract (i.e. pancreatic masses, mediastinal masses, perirectal masses and lymph nodes).
Device Regulatory Classification	21 CFR 876.4300	21 CFR 876.1075	21 CFR 876.1075
Product Code	KGE	FCG	FCG
Device Class	2	2	2
510(k) number	K101657	K212423	K180449
Guidance method	Endoscopy-Optic	Endoscopy-Optic/Ultrasound	Endoscopy Optic/Ultrasound
Tip dimensions	2,20 mm (14 Gauge)	1,47 mm (17 Gauge)	19-25 Gauge
Method of tissue dissection	Electrically heated forceps cuts tissue	Electromechanically rotated cylinder cuts tissue.	Manually moved beveled needle tip cuts tissue
Method of tissue collection	Electrically heated forceps cuts, severs and collects tissue	Electromechanically rotated cylinder cuts, severs and collects tissue.	Cutting needle tip severs and removes tissue into hollow needle. Vacuum assisted
Patient contact materials	Stainless steel; surgical-grade plastic	Stainless steel; surgical-grade plastic	Nitinol; Stainless steel; surgical-grade plastic

Outer sheath adjustment	Forceps and sheath positioned and length adjusted by hand	Outer sheath positioned and length adjusted by hand. Length locked with screw	Outer sheath positioned and length adjusted by hand. Length locked with screw
Inner tip adjustment	Forceps tip positioned and opened/closed with handle	Cylinder tip positioned and length adjusted/locked with needle stopper knob	Needle tip positioned and length adjusted/locked with needle stopper knob
Power source	DC electrosurgical unit Electrical power connected to biopsy forceps instrument via a cord from DC electrosurgical unit. 3V DC high frequency	DC Motor, electromechanical driven rotation No electrical power connected to instrument or patient. Rotation is mechanically transferred to handle via isolated drive cable. 110V AC	Manual
Hand-held procedure?	Yes	Yes	Yes
Single use disposable device vs. reusable device	Single use, disposable hot biopsy forceps and handle; reusable electrosurgical unit and power cord	Single use, disposable cylinder needle and handle; reusable motor and drive cable	Single use, disposable biopsy needle

PERFORMANCE TESTING - (NON-CLINICAL) BENCH

The EndoDrill® Model X System has been determined to be substantial equivalent to the predicate device. Side by side engineering bench testing have been performed to support substantial equivalence with the reference predicate device. These tests showed that the EndoDrill® Model X to meets applicable ISO, and FDA safety and performance standards,

Non-clinical bench performance testing completed:

- Engineering comparative testing including:
  - Evaluate effectiveness of
    - Advance of needle
    - Retreat of stylet
    - Visibility of needle
    - Retreat of needle
    - Withdrawal from endoscope
    - Repetition test
    - Needle durability, including bending
    - Proper functioning of motor, drive train and controls during penetration passes through surrogate tissues
    - Ultrasound compatibility

        - Endoscope compatibility
        - Locking mechanisms for outer sheath-and needle adjustment
        - Tissue penetration
        - Tissue collecting
        - Tissue transport
        - Tissue artefacts (heat/burning/crusch) due to rotation
    - Determine Tissue penetration force
    - Sample acquisition
    - Evaluate Tissue harvesting mechanisms
        - Over pressure method (air)
        - Fluid flush
        - Mandril
        - Transport of multiple samples
    - Compare quality of samples collected
- Engineering testing
    - Performance testing
        - Drive motor
        - Drive Cable
        - Drive motor controls
    - Sterilization/Shelf Life testing
    - Biocompatibility
    - IEC 60601 Electrical safety and EMC

PERFORMANCE TESTING – ANIMAL

There are no animal data submitted with this Notification.

PERFORMANCE TESTING – CLINICAL

There are no clinical data submitted with this Notification.

CONCLUSION:

Based on the results of non-clinical (bench) testing, the EndoDrill® Model X System performs safely and as intended. Regarding comparison of intended use and technological characteristics, it is determined that the EndoDrill® Model X System is substantially equivalent to the predicate device.