May 24, 2019

Bioncise NV
Jaak Janssens
CEO
Bodemstraat 16
Wellen, Limburg
Belgium 3830

Re: K190378
Trade/Device Name: Spirotome Endo 08 Gauge, Spirotome Endo 10 Gauge, Spirotome Endo 14 Gauge, Spirotome Endo 14 Gauge with 10 mm Helix
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: QHC
Dated: February 20, 2019
Received: February 25, 2019

Dear Jaak Janssens:

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,

Sharon Andrews
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)*
K190378

Device Name
Spirotome Endo 08 Gauge, Spirotome Endo 10 Gauge, Spirotome Endo 14 Gauge, Spirotome Endo 14 Gauge with 10 mm Helix

Indications for Use *(Describe)*
The Spirotome Endo is a family of large core soft tissue biopsy medical devices to be used in humans to take out adequate samples of tissue.

The Spirotome Endo is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities of the internal female reproductive organs such as uterus, ovaries, and retroperitoneal lymph nodes.

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
K190378

Submitter Information:

Bioncise NV
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Contact:

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Date prepared: May 23, 2019

Device Identification:

Trade Name:	Spirotome Endo 08 Gauge, Spirotome Endo 10 Gauge, Spirotome Endo 14 Gauge, Spirotome Endo 14 Gauge with 10 mm Helix
Common Name:	Core Biopsy Instrument
Regulation Number:	21 CFR 876.1075
Regulation Name:	Gastroenterology-Urology Biopsy Instrument
Product Code:	QHC
Regulatory Class:	Class II

Predicate Device Information

Spirotome Cervicore (K080095)

The predicate device has not been subject to a design-related recall.

Device Description

The Spirotome Endo is a core biopsy device. It consists of a stainless steel receiving needle with a helical shape, stainless steel cutting cannula, and a polypropylene releasing element. The receiving needle is inserted though the cutting cannula prior to advancing to the biopsy site. The receiving needle is rotated clockwise into the tissue using the plastic hub on the proximal end. The cutting cannula is then rotated clockwise to separate the biopsy sample from the surrounding tissue. Following retraction from the biopsy site, the releasing element is used to remove the tissue sample from the receiving needle. The receiving needle is rotated counter-clockwise to release the tissue. The Spirotome Endo is operated manually.

The Spirotome Endo has four variants: one 8 gauge, one 10 gauge, and two 14 gauge needles. The receiving needle is 375 mm in length and the cutting cannula is 325 mm long. The helical needle is 18 mm long in all the variants except one 14 gauge variant, where it is 10 mm long. The device is provided sterile and is for single-use only.

Indications for Use

The Spirotome Endo is a family of large core soft tissue biopsy medical devices to be used in humans to take out adequate samples of tissue.

The Spirotome Endo is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities of the internal female reproductive organs such as uterus, ovaries, and retroperitoneal lymph nodes.

Substantial Equivalence Discussion

Table 1: Substantial Equivalence Comparison

Attribute	Spirotome Endo – Subject Device	Spirotome Cervicore – Predicate Device
Manufacturer	Bioncise NV	Medinvents
510(k) Number	K190378	K080095
Indications for Use	The Spirotome Endo is a family of large core soft tissue biopsy medical devices to be used in humans to take out adequate samples of tissue. The Spirotome Endo is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities of the internal female reproductive organs such as uterus, ovaries, and retroperitoneal lymph nodes.	The Cervicore system is a family of core soft tissue biopsy medical devices to be used in humans to take out adequate samples of tissue from the human cervix. The Cervicore system is intended to provide soft tissue for histological and biomolecular detection and confirmation of imaged abnormalities by inspection or colposcopy. The Cervicore system is intended to provide soft tissue for histological and biomolecular detection and confirmation of palpable abnormalities. An early detection and correct diagnosis is a prerequisite for a successful multimodality treatment of malignant disease. Therefore, an adequate sampling of human tissue is necessary to make a reliable diagnosis of benignancy or malignancy and to characterize as complete as possible the nature of the lesion without unnecessary discomfort to the patient. In case of malignancy, a proper multimodality treatment is necessary i.e. surgery and/or chemotherapy and/or hormone therapy and/or biological therapy. In case of benignancy, adequate follow-up of the patient can be provided.
Biopsy Tissue Types	Uterine, ovarian, and retroperitoneal lymph nodes	Cervical
Needle Gauge	8, 10, 14 g	8, 10, 14 g

Device Components	Cutting Cannula Receiving Needle Releasing Element	Cutting Cannula Receiving Needle Releasing Element
Helical Needle Length	10, 18 mm	10, 20 mm
Component Length	Receiving Needle: 375 mm Cutting Cannula: 325 mm	Receiving Needle: 384.5 mm Cutting Cannula: 350 mm
Device Materials	Stainless steel, polycarbonate, polypropylene	Stainless steel, polycarbonate, polypropylene
Sterilization	Steam Sterilized	Steam Sterilized
Number of Uses	Single-use; disposable	Single-use; disposable
Shelf Life	Three years	Three years

The Spirotome Endo and the predicate device (K080095) do not have identical Indications for Use statements. The indication for the subject device includes different biopsy tissue types and does not include statements referring to diagnosis or treatment. This change does not represent a new intended use as the intended use of this device is the same as the predicate – to provide soft tissue biopsy samples.

Non-Clinical Performance Testing

Bench Testing

Bench testing of the subject device, Spirotome Endo, including functional testing, biocompatibility, sterilization and package testing was leveraged from testing conducted on the Spirotome SU (K060384) and Spirotome Cervicore (K080095). The subject device has identical packaging materials, materials of construction, manufacturing, and sterilization processes as the cleared devices.

Literature

As part of demonstrating substantial equivalence to the predicate, literature was provided demonstrating safe and effective use of the subject device for internal female reproductive organs. Clinical use of the Spirotome Endo for gynecological tissues was reported in peer reviewed journals. The reports in clinical literature supported an acceptable safety profile for the subject device during biopsy procedures. The reports did not raise additional concerns regarding the safety and effectiveness of the subject device.

Conclusion

The results of the information and testing described above demonstrate that the Spirotome Endo is as safe and effective as the predicate device and supports a determination of substantial equivalence.