July 1, 2022

Argon Medical Devices
Daniel Lanois
Senior Regulatory Affairs Specialist
1445 Flat Creek Road
Athens, Texas 75751

Re: K213232
Trade/Device Name: Semi-Automatic Biopsy Instrument
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: June 15, 2022
Received: June 16, 2022

Dear Daniel Lanois:

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

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K213232

Device Name
Semi-Automatic Biopsy Intrument

Indications for Use *(Describe)*
The Semi-Automatic Biopsy Instrument and associated Co-Axial Introducer Needle are used to obtain samples from soft tissue such as lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, pancreas, and other masses.

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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared:	June 30, 2022
Company:	Argon Medical Devices, Inc. 1445 Flat Creek Road Athens, Texas 75751 USA Facility Registration number: 1625425
Contact:	Scott Bishop Director Regulatory Affairs Phone: 469-731-1413 Fax: 903-677-9396 Email: scott.bishop@argonmedical.com
Device Trade Name (Subject Device):	Semi-Automatic Biopsy Instrument
Device Common Name:	Biopsy Instrument
Device Classification:	Instrument, Biopsy Product code: KNW 21 CFR 876.1075 Class II Review Panel: Gastroenterology/Urology
Predicate Device(s):	K974814 Argon Medical SuperCore™ Biopsy Instrument
Description of the Device:	The Semi-Automatic Biopsy Instrument is used to obtain soft tissue biopsies. It is composed of a spring-loaded biopsy needle fitted into a plastic handle permitting single handed specimen collection. The position of the needle may be visualized by x-ray, CT, or ultrasound. The needle has numerically ordered centimeter markings to facilitate precise depth placement. The adjustable instrument allows for a specimen notch size of 10mm or 20mm, providing clinical flexibility. The device has an adjustable co-axial adapter built into the device for either the 10mm or 20mm notch settings. The stylet travels up to 27mm from when the device is in a fully charged position (prepared for a collection with the 20 mm notch size) to when the stylet is fully extended. The needle has an echogenic tip. The semi-automatic biopsy instrument is available in several needle gauge sizes and

lengths. The plunger is color coded according to the various gauge sizes, e.g., green=14-gauge, purple=16-gauge, pink=18-gauge, and yellow=20-gauge.

Indication for Use:

The Semi-Automatic Biopsy Instrument and associated Co-Axial Introducer Needle are used to obtain samples from soft tissue such as lung, liver, spleen, kidney, prostate, lymph nodes, breast, thyroid, pancreas, and other masses.

Technological Characteristics:

A comparison of the technological characteristics of the Subject device and the Predicate device demonstrates the Subject device to be substantially equivalent to the current marketed Predicate device.

The Subject device and the Predicate device are based on the following same technological elements:

- Use of an adjustable specimen notch size
- Use of a semi-automatic spring-loaded biopsy needle permitting the stylet to advance prior to firing the cannula
- Use of an echogenic needle tip
- Numerically ordered centimeter markings to facilitate precise depth placement of the needle

The following technological differences exist between the Subject device and the Predicate device:

- Use of a co-axial adapter built into the Subject Device and is not built into the Predicate Device.

	SUBJECT DEVICE	**PREDICATE DEVICE**
	Semi-Automatic Biopsy Instrument	**SuperCore™ Biopsy Instrument**
Manufacturer	Argon Medical Devices, Inc - TX	**SAME**
Gauge Size	14ga, 16ga, 18ga, 20ga	14ga, 16ga, 18ga, 20ga
Lengths	6cm, 10cm, 16cm, 20cm, 25cm (18ga only)	6cm, 9cm, 15cm, 20cm
Notch Size	10mm and 20mm	9.5mm and 19mm
Tip Geometry (Stylet and Cannula)	Bevel	**SAME**
Throw	17mm, 27mm	12mm, 22mm

Echogenicity (Tip)	Yes	**SAME**
Needle Manufacturer	Argon Medical Devices, Inc. - IL	**SAME**
Patient Contacting Materials	Stylet: 304 SS Cannula: 304 SS	**SAME**
Function Type	Semi-Automatic	**SAME**
Disposable	Yes	**SAME**
Performance Testing	• Dimensional • Peak Tensile Strength • Simulated Use (Charging Force, Firing Force, Minimum Firing Force, Dry Firing, Sample Collection) • Shipping Qualification (Product and Packaging Integrity) • Radiopacity • Echogenicity • Corrosion Resistance • Resistance to Breakage / Needle Bending • Accelerated and Real-Time Aging • Penetration Force • Tissue Sampling	• Dimensional • Peak Tensile Strength • Durability of Instrument • Charging Force • Firing Force • Dry Firing (minimum firing force) • Sample Collection • Shipping Qualification
Biological Comparison	Complies to ISO 10993-1:2018 • Cytotoxicity (ISO 10993-5) • Sensitization (ISO 10993-10) • Irritation or - Intracutaneous Reactivity (ISO 10993-10) • Acute Systemic Toxicity (ISO 10993-11) • Material Mediated Pyrogenicity (ISO 10993-11)	Complies to ISO 10993-1:2009 • Cytotoxicity (ISO 10993-5) • Sensitization (ISO 10993-10) • Irritation - Intracutaneous Reactivity (ISO 10993-10)
Intended Shelf-Life	6 months	5 years
Packaging / Shipping ISO 11607	**Biopsy Instrument Only**	**Biopsy Instrument Only**

	• One biopsy device packaged in a Tyvek Pouch **Co-packaged Kit** • One biopsy device, corresponding coaxial introducer needle in a holder packaged in a Tyvek pouch (18ga and 20ga coaxial introducer needles are provided with an additional blunt stylet) 10 pouches and one IFU in each labeled shipping carton	• One biopsy device packaged in a Tyvek Pouch **Co-packaged Kit** • One biopsy device with corresponding coaxial introducer needle, and adaptor packaged in a Tyvek pouch 10 pouches and one IFU in one labeled shelf carton

Equivalence is based upon the product performance, design and intended use. The Subject device and the Predicate device have similar materials of construction, dimensional specifications, design, and sterilization process. This demonstrates that the Subject device is as safe and effective as the Predicate device, and it does not raise different questions of safety and effectiveness than the Predicate device.

Performance Tests (Non-Clinical):

No performance standards have been established under section 514, performance standards, of the Food, Drug and Cosmetic Act for these devices. A series of testing was conducted in accordance with protocols based on requirements outlined in guidance and industry standards and the testing below was shown to meet the acceptance criteria that was determined to demonstrate substantial equivalence.

The following tests were performed under the specified testing parameters to support the Subject device substantial equivalence.

<u>Performance Testing, including:</u>

- Dimensional
- Peak Tensile Strength
- Simulated Use (Charging Force, Firing Force, Minimum Firing Force, Dry Firing, Sample Collection)
- Shipping Qualification (Product and Packaging Integrity)
- Radiopacity
- Echogenicity

- Corrosion Resistance
- Resistance to Breakage / Needle Bending
- Accelerated and Real-Time Aging
- Penetration Force
- Tissue Sampling

Biocompatibility Testing, including:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation or - Intracutaneous Reactivity (ISO 10993-10)
- Acute Systemic Toxicity (ISO 10993-11)
- Material Mediated Pyrogenicity (ISO 10993-11)

Substantial Equivalence:	Based on the Indication for Use, design, and safety and performance testing, the Subject device meets the requirements for its intended use and is substantially equivalent to the Predicate device.
Conclusion:	The results of all testing demonstrate that the Subject device is substantially equivalent to the Predicate device.