



February 23, 2026

Argon Medical Devices, Inc.
Jacquelyn Huyghue
Sr. Regulatory Affairs Specialist
1445 Flat Creek Road
Athens, Texas 75751

Re: K252795

Trade/Device Name: ZeniCore™ Automatic Biopsy Instrument (863212100 / ZeniCore Automatic Biopsy Device 12ga x 10cm with Coaxial Introducer Kit); ZeniCore™ Automatic Biopsy Instrument (863212130 / ZeniCore Automatic Biopsy Device 12ga x 13cm with Coaxial Introducer Kit); ZeniCore™ Automatic Biopsy Instrument (863214100 / ZeniCore Automatic Biopsy Device 14ga x 10cm with Coaxial Introducer Kit); ZeniCore™ Automatic Biopsy Instrument (863214130 / ZeniCore Automatic Biopsy Device 14ga x 13cm with Coaxial Introducer Kit); ZeniCore™ Automatic Biopsy Instrument (863214160 / ZeniCore Automatic Biopsy Device 14ga x 16cm with Coaxial Introducer Kit); ZeniCore™ Automatic Biopsy Instrument (863216100 / ZeniCore Automatic Biopsy Device 16ga x 10cm with Coaxial Introducer Kit); ZeniCore™ Automatic Biopsy Instrument (863216160 / ZeniCore Automatic Biopsy Device 16ga x 16cm with Coaxial Introducer Kit)

Regulation Number: 21 CFR 876.1075

Regulation Name: Gastroenterology-Urology Biopsy Instrument

Regulatory Class: Class II

Product Code: KNW

Dated: January 23, 2026

Received: January 23, 2026

Dear Jacquelyn Huyghue:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JESSICA CARR -S

Jessica Carr, 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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252795

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Please provide the device trade name(s).

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ZeniCore™ Automatic Biopsy Instrument (863212100 /
ZeniCore Automatic Biopsy Device
12ga x 10cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863212130 /
ZeniCore Automatic Biopsy Device
12ga x 13cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863214100 /
ZeniCore Automatic Biopsy Device
14ga x 10cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863214130 /
ZeniCore Automatic Biopsy Device
14ga x 13cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863214160 /
ZeniCore Automatic Biopsy Device
14ga x 16cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863216100 /
ZeniCore Automatic Biopsy Device
16ga x 10cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863216160 /
ZeniCore Automatic Biopsy Device
16ga x 16cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863216200 /
ZeniCore Automatic Biopsy Device
16ga x 20cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863218100 /
ZeniCore Automatic Biopsy Device
18ga x 10cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863218160 /
ZeniCore Automatic Biopsy Device
18ga x 16cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863218200 /
ZeniCore Automatic Biopsy Device
18ga x 20cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863218250 /
ZeniCore Automatic Biopsy Device
18ga X 25cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863220100 /
ZeniCore Automatic Biopsy Device
20ga x 10cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863220160 /
ZeniCore Automatic Biopsy Device
20ga x 16cm with Coaxial Introducer Kit);
ZeniCore™ Automatic Biopsy Instrument (863220200 /
ZeniCore Automatic Biopsy Device
20ga x 20cm with Coaxial Introducer Kit);

ZeniCore™ Automatic Biopsy Instrument (863112100 /
ZeniCore Automatic Biopsy Device 12ga X 10cm);
ZeniCore™ Automatic Biopsy Instrument (863112130 /
ZeniCore Automatic Biopsy Device 12ga X 13cm);
ZeniCore™ Automatic Biopsy Instrument (863114100 /
ZeniCore Automatic Biopsy Device 14ga x 10cm);
ZeniCore™ Automatic Biopsy Instrument (863114130 /
ZeniCore Automatic Biopsy Device 14ga x 13cm);
ZeniCore™ Automatic Biopsy Instrument (863114160 /
ZeniCore Automatic Biopsy Device 14ga x 16cm);
ZeniCore™ Automatic Biopsy Instrument (863116100 /
ZeniCore Automatic Biopsy Device 16ga x 10cm);
ZeniCore™ Automatic Biopsy Instrument (863116160 /
ZeniCore Automatic Biopsy Device 16ga x 16cm);
ZeniCore™ Automatic Biopsy Instrument (863116200 /
ZeniCore Automatic Biopsy Device 16ga x 20cm);
ZeniCore™ Automatic Biopsy Instrument (863118100 /
ZeniCore Automatic Biopsy Device 18ga x 10cm);
ZeniCore™ Automatic Biopsy Instrument (863118160 /
ZeniCore Automatic Biopsy Device 18ga x 16cm);
ZeniCore™ Automatic Biopsy Instrument (863118200 /
ZeniCore Automatic Biopsy Device 18ga x 20cm);
ZeniCore™ Automatic Biopsy Instrument (863118250 /
ZeniCore Automatic Biopsy Device 18ga X 25cm);
ZeniCore™ Automatic Biopsy Instrument (863120100 /
ZeniCore Automatic Biopsy Device 20ga x 10cm);
ZeniCore™ Automatic Biopsy Instrument (863120160 /
ZeniCore Automatic Biopsy Device 20ga x 16cm);
ZeniCore™ Automatic Biopsy Instrument (863120200 /
ZeniCore Automatic Biopsy Device 20ga x 20cm)

Please provide your Indications for Use below.

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The ZeniCore™ Automatic Biopsy Instrument and optional Co-Axial Introducer Needle is a single-use device indicated for obtaining core samples of soft tissue masses via percutaneous needle biopsy. It is not intended for use in bone.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

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Date Prepared: February 20, 2026

General Provisions	Submitter Name:	Argon Medical Devices, Inc
	Address:	1445 Flat Creek Road Athens, Texas 75751 USA
	Facility Registration Number:	1625425
	Contact Name:	Jacquelyn Huyghue Sr. Regulatory Affairs Specialist
	Telephone Number:	(412) 568-3369
	Email:	Jacquelyn.huyghue@argonmedical.com

Subject Device	Trade Name:	ZeniCore™ Automatic Biopsy Instrument
	Common/Usual Name:	Instrument, biopsy
	Classification Name:	Gastroenterology-urology biopsy instrument
	Device Classification:	2
	Product Code:	KNW
	Regulation:	21 CFR 876.1075
	Review Panel:	General and Plastic Surgery

Predicate Device	Trade Name:	Tru-Core II Automatic Biopsy Instrument
	Classification Name:	Gastroenterology-urology biopsy instrument
	Premarket Notification:	K982960
	Manufacturer:	Medical Device Technologies, Inc.

Reference Device	Marquee™ Disposable Core Biopsy Instrument K133948 Manan General Purpose Introducer Needle K980004 (Coaxial Introducer Needle)
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Device Description	<p>The ZeniCore™ Automatic Biopsy Instrument and optional, coaxial Introducer needle is a single-use medical device intended for obtaining core soft tissue samples via percutaneous needle biopsy. It is not intended for use in bone lesions. The ZeniCore™ Automatic Biopsy Instrument is a sterile, single patient use device comprised of a spring-loaded biopsy needle fitted into a plastic handle permitting single handed specimen collection than can be used with an optional corresponding coaxial Introducer Needle. The position of the needle may be visualized by imaging techniques such as X-ray, fluoroscopy, and ultrasound. The needle has an echogenic tip with numerically ordered centimeter markings to facilitate precise depth placement. The throw length of the needle when collecting a specimen is 25mm. There are five available needle gauge (G) sizes (12G, 14G, 16G, 18G and 20G) which are identified by a color-coded actuator button. The device is sold either standalone, or as a kit, with an optional, corresponding coaxial needle (cleared under K980004).</p>
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Indications for Use	The ZeniCore™ Automatic Biopsy Instrument and optional Co-Axial Introducer Needle is a single-use device indicated for obtaining core samples of soft tissue masses via percutaneous needle biopsy. It is not intended for use in bone.
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Comparison to Predicate Device	Equivalence is established on ex vivo tissue performance testing, same intended use, mechanism of action, sterilization method, sample method, visualization technique, Materials commonly used for medical devices that meet ISO 10993-1:2020, comparable indications for use, comparable technological characteristics, equivalent principle of operation and design features,
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**510(k) Summary - K252795
ZeniCore™ Automatic Biopsy Instrument**

	Subject Device	Primary Predicate	Reference Predicate	Reference Predicate
	ZeniCore™ Automatic Biopsy Instrument	Tru-Core II Automatic Biopsy Instrument K982960	Marquee™ Disposable Core Biopsy Instrument K133948	Coaxial Introducer Needle K980004 (new SKU's added)
Manufacturer	Argon Medical Devices, Inc.	Argon Medical Devices, Inc. (formerly Medical Device Technologies, Inc)	Becton Dickinson (formerly Bard)	Argon Medical Devices, Inc.
FDA Clearance	TBD	K982960	K133948	K980004
Class	2	Same	Same	Same
Device Classification Name	Instrument, biopsy	Same	Same	Same
Regulation	876.1075	Same	Same	Same
Product Code	KNW	Same	Same	Same
Clinical Comparison				
Intended Use	The ZeniCore™ Automatic Biopsy Instrument and optional Co-Axial Introducer Needle is a single-use device designed to obtain tissue samples from the body. It is not intended for use in bone	Same – intended to collect tissue samples The Tru-Core™ II Automatic Biopsy Instrument is used to obtain multiple core samples from soft tissue such as liver, kidney, prostate, breast, etc. and not intended for bone.	Same – intended to collect tissue samples The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone..	Co-Axial Introducer Needle is used with either a side notch or full core biopsy needle device in performing soft tissue percutaneous biopsies.

**510(k) Summary - K252795
ZeniCore™ Automatic Biopsy Instrument**

	Subject Device	Primary Predicate	Reference Predicate	Reference Predicate
	ZeniCore™ Automatic Biopsy Instrument	Tru-Core II Automatic Biopsy Instrument K982960	Marquee™ Disposable Core Biopsy Instrument K133948	Coaxial Introducer Needle K980004 (new SKU's added)
Principle of Operation	<p>Before inserting the biopsy device into the patient, the device is charged/cocked and ready for use. After the target area is determined and the access site is identified, the area of interest on the patient where the biopsy will occur is locally anaesthetized. An optional coaxial needle is inserted percutaneously either via an incision in the patient's skin by a scalpel or by the coaxial needle itself. After penetration of the patient's skin, the coaxial needle is advanced proximal to the target with the aid of imaging (Ultrasound, Fluoroscopy or CT). The biopsy device is then inserted into the needle and advanced proximal to the target area with the aid of imaging. After the device is positioned correctly based on the physician, the biopsy device is then discharged/fired to collect the specimen and is then removed from the patient. The specimen is expelled removed from the device onto a collection slide and/or</p>	<p>Similar – biopsy tissue sample(s) Slide the cannula knob proximally until the mechanism “clicks” into place. Slide the stylet knob proximally until the mechanism “clicks” into place. The device is now ready for use; insert needle proximal to area to be sampled. Warning: Be careful not to push stylet thumb knob until needle is inserted to desired location. Verify proper location of needle. Slide stylet knob forward until device fires. Withdraw the needle from the biopsy site. To remove the biopsy specimen from the needle, engage the cannula knob until the mechanism “clicks” into place</p>	<p>Similar – biopsy tissue sample(s) The biopsy procedure must be performed using appropriate aseptic techniques. 1. Prepare the site as required. Adequate anesthesia should be administered prior to incision of the skin. 2. Verify instrument is energized (cocked). 3. Using the penetration depth switch, select the desired penetration depth (18mm or 25mm). The default setting is 25mm. 4. Insert the tip of the needle prior to the lesion to be biopsied. 5. While maintaining the instrument's position and the needle orientation, fire the instrument in either Automatic or Semi-Automatic mode. 5a. Automatic Mode – Press the “A” trigger to sequentially fire the stylet and cutting cannula to automatically capture the biopsy specimen 5b. Semi-automatic Mode – Press the “S” trigger to fire only the stylet. With imaging, the user can verify the sample notch is in the target area to be biopsied. When ready to capture the biopsy specimen, press the “A” trigger to advance the cutting cannula</p>	<ol style="list-style-type: none"> 1. Prepare the biopsy site appropriately and locate the target area. 2. Advance a Co-axial Introducer Needle, using standard technique, to a position proximal to the lesion. Position the adjustable needle stop proximal to the skin. 3. Remove the stylet from the Co-axial Introducer Needle, leaving the cannula in position. 4. Choose your complementary biopsy needle. 5. Insert the biopsy needle through the coaxial needle. 6. Fire and retrieve the biopsy sample with the biopsy needle. 7. Removed the biopsy needle.

**510(k) Summary - K252795
ZeniCore™ Automatic Biopsy Instrument**

	Subject Device	Primary Predicate	Reference Predicate	Reference Predicate
	ZeniCore™ Automatic Biopsy Instrument	Tru-Core II Automatic Biopsy Instrument K982960	Marquee™ Disposable Core Biopsy Instrument K133948	Coaxial Introducer Needle K980004 (new SKU's added)
	placed into fixative for pathological evaluation. If additional samples are needed, the biopsy device is re-charged, reinserted into patient, discharged/fired to collect specimen, and removed from patient. When the collection of samples is finished and if used, the coaxial needle (if utilized) is removed from the patient and disposed.		6. Remove needle from patient. Pull back on the energizing slide once to lock the cutting cannula and expose the sample notch to acquire the biopsy specimen. 7. If additional biopsies are required, pull back on the energizing slide once more to lock the stylet and return to step 5.	
Mechanism of Action	Mechanical – spring operated	Same	Same	Same
Indication for Use	The ZeniCore™ Automatic Biopsy Instrument and optional Co-Axial Introducer Needle is a single-use device indicated for obtaining core samples of soft tissue masses via percutaneous needle biopsy. It is not intended for use in bone.	Comparable – core samples from soft tissues The Tru-Core™ II Automatic Biopsy Instrument is used to obtain multiple core samples from soft tissue such as liver, kidney, prostate, breast, etc and not intended for bone	Comparable– core samples from soft tissues The core needle biopsy device is intended for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.	Co-Axial Introducer Needle is intended for a range of biopsy applications of soft tissue.
Contraindication	<ul style="list-style-type: none"> Uncorrected coagulopathy Inability to obtain a safe access route 	Similar – stated in “Warnings” in Subject device For use only for core biopsies of soft tissue as determined by a licensed physician. The instrument should be used by a physician familiar	Similar – stated in “Warnings” in Subject device Good medical judgment should be exercised in considering biopsy on patients who are receiving anticoagulant therapy or who have bleeding disorders	Not Specified

510(k) Summary - K252795
ZeniCore™ Automatic Biopsy Instrument

	Subject Device	Primary Predicate	Reference Predicate	Reference Predicate
	ZeniCore™ Automatic Biopsy Instrument	Tru-Core II Automatic Biopsy Instrument K982960	Marquee™ Disposable Core Biopsy Instrument K133948	Coaxial Introducer Needle K980004 (new SKU's added)
		with the possible side effects, typical findings, limitations, indications and contraindications of core needle biopsy. Physician judgment is required when considering biopsy on patients with bleeding disorder, or receiving anticoagulant medication		
Target Patient Population	Adults requiring biopsy of soft tissue masses	Not Specified	Similar Individuals requiring biopsy for sampling of soft tissue abnormalities	Not Specified
Single Use	Yes	Same	Same	Same
Supplied Sterile	Minimum SAL 10 ⁻⁶ , EtO	Same EtO	Same	Same
Device Description	The ZeniCore™ Automatic Biopsy Instrument is a sterile, single patient use device comprised of a spring-loaded biopsy needle fitted into a plastic handle permitting single handed specimen collection than can be used with a corresponding Co-Axial Introducer Needle. The position of the needle may be visualized by imaging techniques such as X-ray, fluoroscopy, and ultrasound. The needle has an echogenic tip with numerically ordered centimeter markings to	Similar Device Description: The Tru-Core™ II Automatic Biopsy Instrument has a 22mm throw with a 19mm sample notch. The device includes a spring loaded hand held unit which houses and fires a needle set under the user guidance of two thumb knobs. It is available in various sizes (14, 16, 18 and 20ga) with lengths varying from 10 cm to 25 cm. The 18gax20cm and 18gax25cm instruments are also	Similar The Marquee™ Disposable Core Biopsy Instrument is a single use core biopsy device. It is available in several needle gauge sizes and lengths. The coaxial cannula release is color coded according to the various gauge sizes, e.g., yellow = 20 gauge, pink = 18 gauge, purple = 16 gauge, green = 14 gauge, and light blue = 12 gauge.	The Co-Axial Introducer Needle is intended to be used with a range of biopsy application of soft tissue. The introducer needle provides a clear path that makes it easier to perform multiple biopsies at one site. The Co-Axial Introducer Needle is introduced proximal to the target biopsy site, and then the stylet is removed. The hollow cannula with a standard Luer hub allows for introduction of the biopsy instrument. Each co-axial needle has an echogenic tip for accurate placement under ultrasound



**510(k) Summary - K252795
ZeniCore™ Automatic Biopsy Instrument**

	Subject Device	Primary Predicate	Reference Predicate	Reference Predicate
	ZeniCore™ Automatic Biopsy Instrument	Tru-Core II Automatic Biopsy Instrument K982960	Marquee™ Disposable Core Biopsy Instrument K133948	Coaxial Introducer Needle K980004 (new SKU's added)
	<p>facilitate precise depth placement. The throw length of the needle when collecting a specimen is 25mm. There are five available needle gauge sizes which are identified by a color-coded actuator button. The optional Co-Axial Introducer Needle system includes an outer cannula and an inner stylet which terminate in a trocar tip and serves to support acquisition of tissue samples. Each Co-Axial Introducer Needle has an adjustable spring clip that serves as a locking mechanism to secure the position of the outer co-axial needle relative to the skin which ensures the biopsy needle does not accidentally slide forward or backward during the procedure, thereby maintaining the accuracy and safety of the biopsy. The Luer cap of the stylet is color coded to match the corresponding biopsy instrument it is sized to fit.</p>	<p>available in the URO configuration with the stylet notch upside-down and is specifically for prostate biopsies. The instrument can be used with a corresponding Co-Axial Introducer Needle (packaged and sold separately).</p>		<p>guidance. The combination of stylet and cannula terminate in a trocar type tip. Centimeter markings provide reference for depth placement. Hubs are color coded for easy gauge size determination. Each needle has an adjustable needle stop in the shape of a spring clip which allows the user to restrict the forward movement, effectively localizing the needle tip to the biopsy site</p>
Technological Characteristics				
Needle Gauge Size	12ga, 14ga, 16ga, 18ga, 20ga	Similar 14ga, 16ga, 18ga 20ga	Same 12ga, 14ga, 16ga, 18ga, 20ga	13ga, 14ga, 15ga, 16ga, 17ga and 19ga



510(k) Summary - K252795
ZeniCore™ Automatic Biopsy Instrument

	Subject Device	Primary Predicate	Reference Predicate	Reference Predicate
	ZeniCore™ Automatic Biopsy Instrument	Tru-Core II Automatic Biopsy Instrument K982960	Marquee™ Disposable Core Biopsy Instrument K133948	Coaxial Introducer Needle K980004 (new SKU's added)
Needle Length	10cm, 13cm, 16cm, 20cm, 25cm	Similar 10cm, 16cm, 20cm	Similar 10cm, 13cm, 16cm, 20cm, 25 cm	3.5cm, 3.8cm, 3.9cm, 4.2cm, 4.3cm, 4.6cm, 4.9cm, 5.1cm, 5.4cm, 6.8cm, 7.1cm, 7.5cm, 7.8cm, 9.9cm, 10.2cm, 10.3cm, 10.6cm, 10.9cm, 11.1cm, 11.4cm, 11.5cm, 11.8cm, 12.1cm, 11.2 cm, 4.3cm, 14.6cm, 14.9cm 15.1cm, 15.2cm
Sample Notch Length	19mm	Same 19mm	Similar Notch approx.~17mm (18mm throw length) Notch approx.~19mm (25mm throw length)	N/A
Throw Length	25mm	Similar 22mm	Similar 18mm and 25mm, adjustable throw	N/A
Cannula	Stainless Steel	Same	Same	Same
Sample Retrieval Method	Manual core biopsy using a cutting cannula to capture and retain tissue samples.	Same Manual core biopsy using a cutting cannula to capture and retain tissue samples.	Same Manual core biopsy using a cutting cannula to capture and retain tissue samples.	N/A
Number of Samples	Multiple samples within a single patient	Same	Same	N/A
Mode(s) of Device Operation	Semi-Automatic, Automatic	Similar Automatic	Same Semi-Automatic, Automatic	Similar Automatic
Visualization Techniques	X-ray, fluoroscopy, ultrasound, CT	Same	Same	Same



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	ZeniCore™ Automatic Biopsy Instrument	Tru-Core II Automatic Biopsy Instrument K982960	Marquee™ Disposable Core Biopsy Instrument K133948	Coaxial Introducer Needle K980004 (new SKU's added)
Performance Testing	<ul style="list-style-type: none"> • Visual-Dimensional • Puncture Force • Resistance to Breakage • Charging & Firing Forces • Simulated Use • Tensile • Package Integrity • Tissue Comparison • Radiopacity • Echogenicity • Shipping qualification 	Similar <ul style="list-style-type: none"> • Cocking Force • Visual • Tensile • Dimensional • Radiopacity • Shipping qualification 	Similar <ul style="list-style-type: none"> • Dimensional • Sample quality • Durability • tensile strength • echogenicity 	Similar <ul style="list-style-type: none"> • Tolerance • Corrosion • Radiopacity • Echogenicity • Resistance to breakage • Biopsy Device Compatibility • Luer fitting • Shipping qualification
Non-Clinical, Animal Study	No	Yes	No	
Clinical Study	No	Yes	No	No
Biocompatible	Externally communicating contact with Tissue/bone/dentin Limited Duration (<24hr)	Same	Same	Same
Non-pyrogenic	Yes	Same	Same	Same

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Biological Comparison	<ul style="list-style-type: none"> • Cytotoxicity (ISO 10993-5) • Irritation (ISO 10993-23) • Material Mediated Pyrogen (ISO10993-11) • Sensitization (ISO10993-10) • Guinea Pig Maximization Test (ISO 10993-10) • Acute Systemic Toxicity: Systemic Injection Test (ISO 10993-11) • Hemolysis Test – Direct Contact Method (ISO 10993-4) 	<p>Similar</p> <ul style="list-style-type: none"> • Cytotoxicity (ISO 10993-5) • Irritation (ISO 10993-23) • Material Mediated Pyrogen (ISO10993-11) • Sensitization (ISO10993-10) • Acute Systemic Toxicity: Systemic Injection Test (ISO 10993-11) • Hemolysis Test – Direct Contact Method (ISO 10993-4) 	Not Specified	<p>Similar</p> <ul style="list-style-type: none"> • Cytotoxicity (ISO 10993-5) • Guinea Pig Maximization Test (ISO 10993-10) • Acute Systemic Toxicity: Systemic Injection Test (ISO 10993-11) • Material Mediated Pyrogen (ISO10993-11) • Sensitization (ISO10993-10) • Irritation (ISO 10993-23)
Packaging Configuration	The ZeniCore™ Automatic Biopsy Instrument is packaged in a PETG form-fill-seal tray sealed with a Tyvek lid, designed to maintain sterility and protect the device during handling and transport. Each tray—regardless of device configuration—is	<p>Similar</p> <p>The Tru-Core™ II is provided in a tray with a tyvek lid and terminally sterilized using ethylene oxide gas (EtO). The packaging configuration consists of coated 2FS Tyvek sealed to a blue tint PETG tray. Five (5) instruments are placed along with the instructions for use in a shelf box and labeled.</p>	<p>Similar</p> <p>6 blister packs with Tyvek lids in a cardboard shelf box with the IFU</p>	The optional coaxial needles are packaged in Tyvek pouches, which are then boxed in a corrugated shipper in quantities of ten per shipper, including one IFU per box.



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	ZeniCore™ Automatic Biopsy Instrument	Tru-Core II Automatic Biopsy Instrument K982960	Marquee™ Disposable Core Biopsy Instrument K133948	Coaxial Introducer Needle K980004 (new SKU's added)
	packaged in the same size tray and sealed individually, then grouped into shipper corrugate boxes of five units. One Instructions for Use (IFU) document is included per box. These boxes are ETO (ethylene oxide) sterilized			
Materials	All materials are commonly used for this type of medical device and are biocompatible in accordance with ISO 10993-1.	Same	Unknown	Same
Sterilization	Minimum SAL 10 ⁻⁶ , EtO	Same	Same	Same
Shelf-Life	5 years	Same	3 years	Same

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 below were shown to meet the acceptance criteria that were determined to demonstrate substantial equivalence.

The following tests were performed under the specified testing parameters to support the ZeniCore™ Automatic Biopsy Instrument and optional coaxial introducer needle to establish substantial equivalence:

**Non-Clinical Data
(Bench-top Testing)**

- Visual
- Dimensional
- Puncture Force
- Resistance to breakage
- Charging and Firing Force
- Simulated Use conducted in three different ex vivo animal tissues
- Tensile
- Package Integrity
- Tissue Composition (biopsy) conducted in three different ex vivo animal tissues
- Radiopacity
- Echogenicity
- Corrosion
- Design Validation and Summative Usability

Biocompatibility has been established for the ZeniCore™ Automatic Biopsy Instrument and optional, coaxial introducer needle according to ISO 10993-1:2018 as an externally communicating device in contact with Tissue/bone/dentin for limited Duration (<24hr).

A review of the material characteristics and manufacturing processes of the ZeniCore™ Automatic Biopsy Instrument and optional, coaxial introducer needle was conducted in comparison with Argon Medical like devices with the same materials, manufacturing processes, processing agents, and the same sterilization cycle (2X EtO Sterigenics Cycle 722). As previously evaluated for biocompatibility using final, finished and sterilized devices based on ISO 10993-1, analysis determined re-testing not required and a rationale has been provided. The following studies were all studies previously performed following the approved protocol under Good Laboratory Practices (GLP) in compliance to FDA GLP, 21 CFR Part 58.

**Non-Clinical Data
Biocompatibility**

Biocompatibility Testing included:

- Cytotoxicity (ISO 10993-5)
- Irritation (ISO 10993-23)
- Material Mediated Pyrogen (ISO10993-11)
- Sensitization (ISO10993-10)
- Guinea Pig Maximization Test (ISO 10993-10)
- Acute Systemic Toxicity: Systemic Injection Test (ISO 10993-11)
- Hemolysis Test – Direct Contact Method (ISO 10993-4)

**Substantial
Equivalency
Conclusion**

The optional, coaxial introducer introduces no additional clinical risk, based upon the literature review, comparable indication for use, same intended use, mechanism of action, sterilization method, sample retrieval method, visualization technique and equivalent principle of operation.



510(k) Summary - K252795
ZeniCore™ Automatic Biopsy Instrument

Based on performance testing in ex vivo tissue and comparable indications for use, same intended use, comparable principle of operation, materials, technological characteristics, design features and sterilization process; the ZeniCore™ Automatic Biopsy Instrument is substantially equivalent to the predicate devices.
