September 24, 2025

Resitu Medical AB
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K252183
Trade/Device Name: Resitu Slider 09 (RESL09)
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: July 11, 2025
Received: July 11, 2025

Dear Janice Hogan:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 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 systems (QS) regulation (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, PhD
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252183

Device Name
Resitu Slider 09 (RESL09)

Indications for Use *(Describe)*
Resitu Slider 09 is intended to provide breast tissue for diagnostic analysis of imaged abnormalities.

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 - K252183

Resitu Medical AB's Resitu Slider 09 (RESL09)

Submitter:

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Date Prepared: September 15, 2025

Name of Device: Resitu Slider 09

Classification Name: Gastroenterology-Urology Biopsy Instrument

Regulatory Class: II

Product Code: KNW

Predicate Device: Intact® Gen2 System (K152596)

Reference Device: Mammotome® Elite Biopsy System (K153709)

DEVICE DESCRIPTION

Resitu Slider 09 (RESL09) is a minimally invasive, vacuum assisted device, intended to provide large intact breast tissue samples for histologic examination of imaged abnormalities. The device is provided sterile and is for single-use. Resitu Slider 09 is hand-held (vacuum is created in the handle) and is part of a monopolar high frequency electrosurgical system.

The intended sample site is reached via a skin incision followed by blunt penetration under ultrasound guidance. The sample capture relies on a combination of vacuum that fixates the sample and cutting with a circular knife. While cutting around the sample area, the vacuum allows the whole tissue sample to enter into the tube of the device. An electrosurgical electrode, designed to mimic a mechanical cutting blade, severs the top base of the breast tissue sample from surrounding area. The device is withdrawn with the intact breast tissue sample inside the tube.

The device functions as an active accessory by passing energy that is controlled by the electrosurgical generator to the tissue, similar to other electrosurgical tools.

The Resitu Slider 09 electrosurgical system consists of the following:

- Active Accessory (Monopolar)
- Electrosurgical Unit
- Active Accessory Cord

- Neutral Electrode
- Neutral Electrode Connection Cord
- Foot Switch (Pedal)

The device consists of a plastic handle, to which a transparent tube with a circular stainless steel knife at the end is attached. Inside the tube is a rod that creates a blunt end when in its outer position. The rod can be pulled back to expose the circular knife and create a vacuum, which will assist in excising the tissue, inside the tube.

In the center of the tube is an electrode, a diathermic knife, which can be pushed forward, backwards, and also turn 360 degrees, thereby enabling a radial cutting from the center.

INDICATIONS FOR USE

Resitu Slider 09 is intended to provide breast tissue for diagnostic analysis of imaged abnormalities.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

RESL09 has the same general intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicate device, Intact® Gen2 System (K152596).

Both RESL09 and the Intact® Gen2 System are sterile, single-use, ultrasound-guided electrosurgical breast biopsy devices intended to retrieve large, intact breast tissue specimens for histological evaluation. The two systems are based on the same fundamental scientific principles and core technological characteristics:

- Both devices use monopolar electrosurgical energy to excise tissue specimens from the breast and to support hemostasis during the biopsy procedure.
- Both utilize stainless steel cutting elements and electrosurgical activation to detach the specimen.
- Both are used with ultrasound guidance to assist in accurate placement and targeting of tissue abnormalities.
- Both preserve lesion architecture, enabling histological assessment of intact samples.
- Both devices are designed for single insertion and retrieve a single, intact tissue specimen.
- Both devices are packaged sterile for single use and constructed from validated biocompatible materials compliant with ISO 10993 standards.

Moreover, design differences do not raise different questions of safety or effectiveness. Performance test data demonstrate RESL09's ability to safely and effectively achieve its intended use and support its substantial equivalence to the predicate. A table comparing the key features of the subject, predicate, and reference devices is provided below.

PERFORMANCE DATA

Resitu Medical AB conducted a series of non-clinical performance studies to assess the safety, functionality, and usability of the RESL09 breast biopsy device.

- Bench verification testing
- Biocompatibility testing according to ISO 10993-1, including cytotoxicity, irritation, sensitization, material mediated pyrogenicity, and acute systemic toxicity testing
- Sterilization, packaging, and shelf life testing
- Electrical safety and electromagnetic compatibility testing according to IEC 60601-1, IEC 60601-2-2, IEC 60601-1-6 and IEC 60601-1-2
- Human factor testing
- *In vivo* and *ex vivo* studies, as shown below.

In Vivo Porcine Study

An acute study in five (5) pigs was conducted to assess RESL09 safety and performance compared to Mammotome Elite®. Each animal received two biopsies per device. One animal was excluded from analysis due to procedural deviations, resulting in 16 evaluable biopsies (8 per device).

Key findings included:

- RESL09 retrieved single, intact biopsy specimens.
- RESL09 was consistently visible under ultrasound guidance.
- No acute adverse events or device-related safety concerns were noted.

Human Ex Vivo Breast Tissue Study

A controlled laboratory study was performed using freshly excised human breast tissue from reduction mammoplasty procedures. RESL09 and Mammotome were each used to collect biopsy samples from donor tissue, with a total of 39 biopsies performed (21 with RESL09, 18 with Mammotome).

Key findings included:

- All RESL09 samples (21/21) were determined to be of sufficient quality and quantity for histological analysis, with the success rate exceeding the pre-specified performance goal.
- Immunohistochemical (IHC) staining quality was comparable across epithelial, stromal, and endothelial markers.
- No adverse events or device-related issues were observed.

CONCLUSION

RESL09 is as safe and effective as the predicate device Intact® Gen2 System (K152596). The subject device has the same intended use and similar indications for use, technological characteristics, and principles of operation. The minor differences in indications do not alter the intended clinical use of the device as compared to its predicate, nor do they affect its safety and effectiveness when used as intended. In addition, the minor technological differences between RESL09 and its predicate raise no new questions of safety or effectiveness. Performance data demonstrates that the subject device functions as intended and further supports substantial equivalence.

	Resitu Slider 09	Intact® Gen2 System (K152596)	Mammotome Elite® Biopsy System (K153709)
Intended use	Resitu Slider 09 is intended to provide breast tissue samples for diagnostic analysis of imaged abnormalities.	The Intact® Gen2 System is indicated to provide tissue samples for diagnostic sampling of breast abnormalities	The Mammotome elite® Biopsy System is intended to provide breast or axillary lymph node tissue samples for diagnostic analysis of imaged or palpated breast abnormalities.
Indications for use	Resitu Slider 09 is intended to provide breast tissue for diagnostic analysis of imaged abnormalities.	The Intact® Gen2 System is indicated to provide tissue samples for diagnostic sampling of breast abnormalities. • The Intact® Gen2 System is intended to provide breast tissue for histologic examination with partial or complete removal of an imaged abnormality. • The Intact® Gen2 System is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality. • The Intact® Gen2 System is intended to preserve lesion architecture in samples with a diameter of 12–30 mm. The extent of a histologic abnormality cannot always be readily determined from palpation or imaged appearance. Therefore, the	The Mammotome elite® Biopsy System is indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. • The Mammotome elite® Biopsy System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. • Mammotome elite® Biopsy System is intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality. The extent of a histologic abnormality cannot always be readily determined from the palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged

	Resitu Slider 09	Intact® Gen2 System (K152596)	Mammotome Elite® Biopsy System (K153709)
		extent of removal of the palpable or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures. In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g., fibroadenoma, fibrocystic lesion), the Intact ® Gen2 System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histologic evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.	evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures. In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (e.g., fibroadenoma, fibrocystic lesion), the Mammotome elite® Biopsy System may also be used to partially remove such palpable lesions. Whenever breast tissue is removed, histological evaluation of the tissue is the standard of care. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.
Imaging guidance	Ultrasound	Ultrasound	Ultrasound or X-ray stereotaxis
Components	Probe and handle, assembled	Probe and handle, assembled	Probe and holster, to assemble

	Resitu Slider 09	Intact® Gen2 System (K152596)	Mammotome Elite® Biopsy System (K153709)
Probe	Tube with a distal circular knife	Wand with 5 small diameter wire electrodes (capture electrode) at the distal end	Outer trocar shaft with distal needle aperture and blade tip, telescoping inner hollow coaxial cutter and coaxial cannula.
Probe Material	Elastomer/ Thermoplastic	Elastomer/ Thermoplastic	Elastomer/ Thermoplastic
Number of probe insertions	Single insertion	Single insertion	Single insertion
Sampling mechanism	Electrosurgical cutting, vacuum pull and transport	Electrosurgical cutting, ensnaring	Rotary cutting, vacuum pull and transport
Sample nature	Single specimen, large specimen	Single specimen, large specimen	Multiple fragments, small cylinders
Sample collection	Specimen contained in the tube	Specimen contained in the capture snare at the distal end of the wand	Proximal specimen collection cup
Harvesting method	Circular knife at the distal end combined to electrosurgical cutting	Metallic hooks, and extensible cutting RF ring wire (capture snare) combined to electrosurgical cutting	Rotation and Translation of Inner Cutter
Cutter/knife Material	Stainless Steel	Stainless Steel	Stainless Steel
Sterility	Sterile, single use	Sterile, single use probe, reusable handle	Sterile, single use probe, reusable holster