March 4, 2026

Devicor Medical Products, Inc.
% Prithul Bom
Regulatory Technology Services, LLC
1000 Westgate Dr. Suite #510k
Saint Paul, Minnesota 55114

Re: K260365

Trade/Device Name: Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Control Module; Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Disposable Probe, 8 gauge; Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Disposable Targeting Set, 8 gauge; Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Foot Switch; Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Reusable Tray; Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Battery Charger; Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Battery; Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Vacuum Canister
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: February 4, 2026
Received: February 4, 2026

Dear Prithul Bom:

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
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.	K260365

Please provide the device trade name(s).

Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Control Module;
Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Disposable Probe, 8 gauge;
Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Disposable Targeting Set, 8 gauge;
Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Foot Switch;
Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Reusable Tray;
Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Battery Charger;
Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Battery ;
Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System Vacuum Canister

Please provide your Indications for Use below.

The Mammotome Prima™ MR Vacuum-Assisted Breast Biopsy System is intended to acquire breast tissue from an imaged abnormality during MRI-guided breast biopsy procedures for histologic examination.

The extent of a histologic abnormality cannot always be reliably determined from an imaged appearance. Therefore, the extent of removal of the 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.

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

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

510(k) Summary - K260365
Devicor Medical Products, Inc. Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System

Submitter:

Devicor Medical Products, Inc.

300 E. Business Way, Fifth Floor, Cincinnati, OH 45241

E-mail: jamie.edenborg@mammotome.com

Contact Person: Jamie Edenborg

Date Prepared: March 2, 2026

Name of Device: Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System

Classification Name: Gastroenterology/Urology Biopsy Instrument

Regulatory Class: II

Product Code: KNW

Predicate Device: Mammotome MR Biopsy System (K042753)

DEVICE DESCRIPTION

The Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System is a battery operated, vacuum-assisted breast biopsy device designed to conduct minimally invasive procedures in the MRI environment. It is intended for use in an MR environment. The system is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The system, used with MR imaging modality, facilitates the diagnostic removal of tissue with fluid management through a combination of vacuum and radial cutting functions. The system is comprised of reusable and disposable components. Reusable components include: a battery-operated cordless control module for in-room use, two batteries and a battery charger, a foot pedal switch, and an optional tray. Disposable components include: an 8 gauge probe; a universal targeting set consisting of a targeting cube, targeting sleeve, obturator cap; and obturator with integrated insertion tip and removable obturator handle.

INTENDED USE [Per 807.92(a)(5)]

The Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System intended for use in an MR environment. The system is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality

INDICATIONS FOR USE

The Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System is intended to acquire breast tissue from an imaged abnormality during MRI-guided breast biopsy procedures for histologic examination.

The extent of a histologic abnormality cannot always be reliably determined from an imaged appearance. Therefore, the extent of removal of the 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.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System has the same general intended use and similar indications for use, technological characteristics, and principles of operation as the previously cleared predicate device, Mammotome MR Biopsy System (K042753).

Both Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System and Mammotome MR Biopsy System use both sterile, single use and reusable components. Primary components for both systems include a probe, targeting set and control module.

Both devices are MR-guided vacuum-assisted breast biopsy devices intended to retrieve breast tissue specimens for histological evaluation. The two systems are based on the same fundamental scientific principles and core technological characteristics:

Both utilize stainless steel cutting elements to excise tissue specimen from the breast.

Both devices facilitate removal and diagnostic sampling of tissue using fluid management through a combination of vacuum and radial cutting functions.

In summary, design differences between the subject and predicate devices do not raise questions of safety or effectiveness. Performance test data demonstrate Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System's ability to safely and effectively achieve its intended use and support the substantial equivalence to the predicate. A table comparing the key features of the subject and predicate devices is provided below.

	Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System	Mammotome MR Biopsy System
Indications for Use	To acquire breast tissue from an imaged abnormality during MRI-guided breast biopsy procedures for histologic examination. The extent of a histologic abnormality cannot always be reliably determined from an imaged appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g.,	To provide tissue samples for diagnostic sampling of breast abnormalities. Intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality and intended to provide breast tissue for histologic examination with partial removal of a palpable abnormality. The extent of a histologic abnormality cannot always be

	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.	readily determined form palpation or imaged appearance. Therefore, the extent of removal of the palpated 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.
Imaging Modality	Magnetic Resonance Imaging	Magnetic Resonance Imaging
Components	Sterile: Targeting Set Probe Reusable: Control Module Footswitch Optional Tray	Sterile: Targeting Set Probe and Vacuum Tube Sets Reusable: Control Module Holster
Sterility	Radiation	Radiation
Use Environment	Inside of the MR Procedure Room	Outside of the MR Procedure Room
Mechanism of Action	Collection of specimens into needle aperture, and excision of specimen, using cutter.	Collection of specimens into needle aperture, and excision of specimen, using cutter.
Specimen Retrieval Method	Automatic Once the tissue specimen is cut, the basket containing specimens can be removed from the probe and entire basket can be placed in formalin.	Manual Once the tissue specimen is cut, a user removes the specimens from the probe with forceps and places them individually into formalin.
Patient Contacting Material	Stainless Steel Polycarbonate PEEK L605 Alloy PVC	Stainless Steel Polycarbonate Liquid Crystal Polymer L605 Alloy PVC

PERFORMANCE DATA

Devicor Medical Products, Inc. conducted a series of non-clinical performance studies to assess the safety, functionality, and usability of the Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System, including:

- Bench verification testing
- Biocompatibility testing according to ISO 10993-1
- 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
- Animal Testing

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary

Performance-Bench

Performance Metrics Bench Testing
Battery charge/discharge reliability
Reusable reliability testing
Targeting set force to penetrate
Targeting Accuracy
MRI Standards
ASTM F2213-17 Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment
ASTM F2182-19e2 Standard test method for measurement of radio frequency induced heating on near passive implants during magnetic resonance imaging
ASTM F2503-23e1 Standard practice for making medical devices and other items for safety in the magnetic resonance environment

Performance-Animal

Performance Metric	**Differences Identified between Mammotome Prima™ MR Dual Vacuum- Assisted Biopsy System and Mammotome MR Biopsy System**	**Success Criteria Met/Not Met**
Sample Weight	Success criteria was met by subject and predicate device**.**	**Met**
Sample Acquisition	**Equivalent** sample acquisition percentage for both subject and predicate device. No failed sample acquisitions observed for either device.	**Met**
Sample Quality	Samples from both subject and predicate device returned pathologist ratings	**Met**

		categorized as excellent diagnostic quality.	
BIOCOMPATIBILITY DATA			
Performance Test Summary			
Biocompatibility	ISO 10993-1:2018-*Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*		
Biocompatibility-Cytotoxicity	ISO 10993-5:2009-*Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity*		
Biocompatibility-Sensitization	ISO 10993-10:2021-*Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization*		
Biocompatibility-Pyrogenicity/Acute Systemic Toxicity	ISO 10993-11:2017-*Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity*		
Biocompatibility-Irritation/Intracutaneous Reactivity	ISO 10993-23:2021 *Biological Evaluation of Medical Devices – Part 23: Tests for Irritation*		

CONCLUSION

Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System is as safe and effective as the predicate device, Mammotome MR Biopsy System (K042753). 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 Mammotome Prima™ MR Dual Vacuum-Assisted Breast Biopsy System 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.