October 29, 2024

Devicor Medical Products, Inc.
% Prithul Bom
Most Responsible person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K243095
Trade/Device Name: Mammotome AutoCore™ Single Insertion Core Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: September 27, 2024
Received: September 30, 2024

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, 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Mammotome AutoCore™ Single Insertion Core Biopsy System

Indications for Use *(Describe)*

The Mammotome AutoCore™ Single Insertion Core Biopsy System is indicated to obtain tissue samples from the breast or lymph nodes for diagnostic analysis of breast abnormalities. This instrument is for diagnostic use only and is not indicated for therapeutic use.

The extent of a histologic abnormality cannot always be reliably determined from the 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.

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.

510(k) SUMMARY A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.	
SUBMITTER INFORMATION	
Name	Devicor Medical Products, Inc.
Address	300 E. Business Way, Fifth Floor, Cincinnati, OH 45241 U.S.A
Establishment Registration Number	3008492462
Name of contact person	Jamie Edenborg
Date prepared	23-JUL-2024
PRODUCT	
Mammotome AutoCore™ Single Insertion Core Biopsy System	
PRODUCT COMPONENTS	
PRODUCT	*DESCRIPTION*
Mammotome AutoCore®Holster and Charging Base	Holster and Charging Base
Mammotome AutoCore® Probe 12 Gauge	Probe 12g x 10cm
Mammotome AutoCore® Probe 14 Gauge	Probe 14g x 10cm
Mammotome AutoCore® Introducer 12 Gauge	Introducer 12g x 10cm
Mammotome AutoCore® Introducer 14 Gauge	Introducer 14g x 10cm
DESCRIPTION OF DEVICE	
Trade or proprietary name	Mammotome AutoCore™ Single Insertion Core Biopsy System
Common or usual name	Core Biopsy System, Single Insertion
Classification name	Instrument, biopsy
Classification panel	Gastroenterology/Urology
Regulation	21 CFR §876.1075
Product code(s)	KNW
Legally marketed device(s) to which equivalence is claimed	K141552 Achieve® Programmable Automatic Biopsy System
Submission Type	Traditional 510(k) Premarket Notification
Device description	The Mammotome AutoCore™ Single Insertion Core Biopsy System is an automated core needle biopsy system. It is a single insertion, multiple sample device that includes automated arming and automated sample collection. It is available in two gauge sizes (12G and 14G) and acquires soft tissue samples using a spring-loaded inner piercing stylet and outer cutting cannula in the probe needle.
Intended use of the device	The Mammotome AutoCore™ Single Insertion Core Biopsy System is intended to obtain tissue samples from the breast or lymph nodes for diagnostic analysis of breast abnormalities.

	This instrument is for diagnostic use only and is not indicated for therapeutic use. The extent of a histologic abnormality cannot always be reliably determined from the 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.

SUMMARY OF THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARED TO THE PREDICATE DEVICE		
Characteristic	**New Device**	**Predicate**
Mode of Action	Single Puncture and Multiple Samples	Single Puncture and Multiple Samples
Firing Modes	Automatic	Automatic and Delay
Anatomical Sites	Breast tissue and lymph nodes	Breast tissue, lymph nodes, kidney, liver, prostate, spleen and various soft tissue masses

CONCLUSION OF DEVICE COMPARISON
A comparison of the technological characteristics of the proposed device and predicate device supports a determination of substantial equivalence.

PERFORMANCE DATA	
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE	
Performance Test Summary	
Characteristic	*Standard/Test/FDA Guidance*
Performance- Bench	Functional testing was performed for comparison of static force to penetrate, lesion displacement, overmold bond strength and bend load to prove substantial equivalence.
Performance- Animal	Animal testing was performed to verify appropriate sample weight, acquisition, and quality.
Software and Electrical Test Summaries	
Characteristic	*Standard/Test/FDA Guidance*

Software	IEC 62304 Edition 1.1 2015-06 Medical Device Software
Electrical	IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance.
Biocompatibility Data	
Characteristic	*Standard/Test/FDA Guidance*
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 10993-10:2010-*Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization*
Biocompatibility- Pyrogenicity/Acute System 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*
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION [Per 807.92(b)(1)(2)(3)]	
N/A – Clinical testing was not required for subject device	
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA	
The verification results and a side-by-side comparison of the technological characteristics of design, indication for use / intended use, components, and materials of construction, supports a determination that the Devicor Medical Products, Inc. Mammotome AutoCore™ Single Insertion Core Biopsy System [subject device] is substantially equivalent to the Achieve® Programmable Automatic Biopsy System (K141552) [predicate device].	