August 18, 2020

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

Re: K202012
Trade/Device Name: Mammotome Revolve Dual Vacuum Assisted Biopsy (VAB) System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: Class II
Product Code: KNW
Dated: July 20, 2020
Received: July 21, 2020

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 (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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202012

Device Name
Mammotome revolve Dual Vacuum Assisted Biopsy (VAB) System

Indications for Use *(Describe)*
The Mammotome revolve Dual Vacuum Assisted Biopsy (VAB) System is indicated to provide tissue samples for diagnostic sampling of breast abnormalities.

• The Mammotome revolve Dual Vacuum Assisted Biopsy (VAB) System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.

• The Mammotome revolve Dual Vacuum Assisted Biopsy (VAB) 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 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.
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 revolve Dual Vacuum Assisted Biopsy (VAB) 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.

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

The following information is provided as required by 21 CFR § 807.92 for the Mammotome revolve EX System 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990 the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Company:

Devicor Medical Products, Inc.
300 E-Business Way, Fifth Floor
Cincinnati, OH 45241
Establishment Registration Number: 3008492462

Contact:

Gwendolyn Payne
Regulatory Affairs Manager
Devicor Medical Products, Inc.
300 E-Business Way, Fifth Floor
Cincinnati, OH 45241
Ph: 513-864-9186
Fax: 513-864-9011
E-mail: Gwendolyn.Payne@mammotome.com

Date of Submission: June 9, 2020

Proprietary Name: Mammotome revolve EX

Common Name: Biopsy System

Regulation: 21 CFR 876.1075

Regulatory Class: II

Product Codes: KNW

Classification Name: Biopsy Instrument

Predicate Device: Mammotome revolve Dual Vacuum Assisted Biopsy (VAB) System, K152989

Device Description: The Mammotome revolve EX System is an electromechanical breast biopsy device indicated to provide tissue samples for diagnostic sampling of beast abnormalities for histologic examination.

The Mammotome revolve EX System is comprised of three primary subsystems:

1) a sterile, single-use Probe
2) a reusable Holster, and
3) a reusable control unit.

Intended Use: The Mammotome revolve Dual Vacuum Assisted Biopsy (VAB) System is indicated to provide tissue samples for diagnostic sampling of breast abnormalities.

- The Mammotome revolve Dual Vacuum Assisted Biopsy (VAB) System is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality.
- The Mammotome revolve Dual Vacuum Assisted Biopsy (VAB) 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 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.

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 revolve Dual Vacuum Assisted Biopsy (VAB) 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.

Technological Characteristics:

The Mammotome revolve EX System facilitates the diagnostic removal of tissue through a combination of vacuum and rotational/translational cutting functions. The Mammotome

revolve EX System utilizes the same primary subsystems as identified in the predicate device to achieve its intended use:

1) a sterile single use Probe containing a trocar tipped biopsy needle, rotating cutter, specimen collection chambers, and vacuum tubing/valving;
2) a reusable Holster, containing the drive motors, gear trains, and user activation switches; and
3) a reusable Control Module, containing the vacuum pump, power supply, valve actuators, user interface touchscreen, control electronics, and software.

In addition, several optional accessories that function with the EX system are available as part of the total Mammotome revolve Dual Vacuum Assisted Biopsy (VAB) System including remote keypad and footswitch controls, a transport cart, and a holster holder for the new EX Holster.

The Mammotome revolve Vacuum Assisted Biopsy (VAB) System has been updated to integrate the new EX system while maintaining the basic technology, functionality and clinical outcomes of the predicate system. Consistent with the Mammotome revolve Dual VAB US System, the EX system is configured for use in the Ultrasound imaging modality.

The system relies on software to operate many of its functions including utilization of closed loop control on cutter position. In both the EX and predicate software systems, the focus of the software is to aid in system set-up and facilitate biopsy functions. The Mammotome revolve EX System software has been updated to include functionality with the new EX Probe.

A side-by-side comparison of the marketed and proposed devices is provided below.

Side-by-Side Comparison to Legally Marketed Device

Table 1a: Side-by-Side Comparison of Mammotome revolve EX Holster and Control Module to previous Mammotome revolve ST and U/S Holsters and Control Module

Device Characteristics: Holster / Control Module	Marketed Device: Mammotome revolve (ST and U/S) Biopsy System (K152989)	Proposed Device: Mammotome revolve (EX) Biopsy System	Comparison: Same, Similiarities, and Differences with Supporting Rationale
Indications for Use	Breast Biopsy / complete, partial removal of imaged abnormality /partial removal of palpated abnormality	Breast Biopsy / complete, partial removal of imaged abnormality /partial removal of palpated abnormality	Same
User interface Mechanisms	Buttons on Holster, Buttons on Remote Keypad, Pedals on Footswitch, Touchscreen	Buttons on Holster, Buttons on Remote Keypad, Pedals on Footswitch, Touchscreen	Same
Microprocessor and upgradeable software	Yes	Yes	Same
Display	Yes, LCD display	Yes, LCD display	Same
Translational Cutter Movement	Automatic	Automatic	Same
Rotational Cutter Movement	Automatic with cutter advancement	Automatic with cutter advancement	Same
Rotational and Translation Speed control	Yes, Closed loop control	Yes, Closed loop control	Same
Drive Train Type	On board Motor and Gear Train	On board Motor and Gear Train	Same
Independent Lateral and Axial Vacuum System	Yes	Yes	Same
Remote Footswitch / Keypad Capability	Yes	Yes	Same

Table 1b: Side-by-Side Comparison of Mammotome revolve EX Probes to previous Mammotome revolve ST and U/S Probes

Device Characteristics: Probes	Marketed Device: Mammotome revolve (ST and U/S) Biopsy System (K152989)	Proposed Device: Mammotome revolve (EX) Biopsy System	Comparison: Same, Similiarities, and Differences with Supporting Rationale
Needle Insertion Method	Fired or Manual	Manual	Same as Mammotome revolve U/S. Mammotome revolve EX offers manual insertion only.
Tip Type	Bladed trocar	Bladed trocar	Same
Tip Material	Stainless steel	Stainless steel	Same
Needle Configuration	Dual lumen	Dual lumen	Same
Needle Material	Stainless steel	Stainless steel	Same
Needle Diameter Sizes	8G and 10G	8G	Same as 8G (ST and U/S)
Vacuum Port Attachment	Yes, tethered to Control Module	Yes, tethered to Control Module	Same
Specimen Retrieval / Collection Method	Automatic	Automatic	Same
Housing Material	Plastic	Plastic	Same

Cutting Method	Rotation and translation of inner cutter	Rotation and translation of inner cutter	Same
Tissue Transport Method	Vacuum	Vacuum	Same
Cutter Material	Stainless steel	Stainless steel	Same
Packaging Type	PETG with Tyvek Cover	LDPE Pouch with Tyvek Header	Different. The difference in packaging material does not raise new or different questions of safety or effectiveness. Sterilization and Shelf Life (Section 15) provides evidence of package integrity and the ability to maintain sterile barrier for this change in packaging type.
Sterilization Method	Cobalt 60 Irradiation	Cobalt 60 Irradiation	Same

The following Performance Data is provided in support of the substantial equivalence (SE) determination.

Summary of Non-Clinical Bench Performance Testing	
Non-Clinical Bench Performance Testing was conducted on the Mammotome revolve EX System [subject device]. The table below includes the list of the performance testing results submitted, referenced, or relied on in this premarket notification submission for a determination of substantial equivalence.	
Sterilization and Shelf Life Testing	
• **Sterility Testing** ***FDA Recognized Testing Standards:*** o ISO 11137-1:2006/AMD 2:2018 - *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilixation*	***Test Results:*** **PASSED** The results of these Non-Clinical Bench Performance Data are provided in support of the substantial equivalence determination. ***Conclusion Supporting Substantial Equivalence:*** The results of the Sterility Testing conducted on the Mammotome revolve EX Probes demonstrates that the subject device is as safe, as effective, and performs as well as, the legally marketed predicate device. This

process for medical devices o ISO 11137-2:2013 - *Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose* o ANSI/AAMI/ISO TIR13004:2013- *Sterilization of health care products — Radiation — Substantiation of a selected sterilization dose: Method* VD_{max}^{SD}	testing supports a determination of substantial equivalence of the Mammotome revolve EX System [subject device] when compared to the Mammotome revolve Vacuum Assisted Biopsy (VAB) System device (K152989) [predicate device].
Biocompatibility Testing	
• **Biocompatibility Testing** including: - Cytotoxicity - Sensitization - Irritation - Acute Systemic Toxicity - Material Mediated Pyrogenicity ***FDA Recognized Testing Standards:*** o *ISO 10993-1:2018-Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process* o ISO 10993-5:2009-*Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity* o ISO 10993-10:2010-*Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization* o ISO 10993-11:2017-*Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity* o ISO 10993-12:2012-*Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials.*	***Test Results:*** **PASSED** The results of these Non-Clinical Bench Performance Data are provided in support of the substantial equivalence determination. ***Conclusion Supporting Substantial Equivalence:*** The results of the Biocompatibility Testing conducted on the Mammotome revolve EX Probes demonstrates that the subject device is as safe, as effective, and performs as well as, the legally marketed predicate device. This testing supports a determination of substantial equivalence of the Mammotome revolve EX System [subject device] when compared to the Mammotome revolve Vacuum Assisted Biopsy (VAB) System device (K152989) [predicate device].

Software Verification and Validation Testing	
• **Functional Testing** including: - Software Unit Testing - System Integration Testing - Software Verification Testing	***Test Results:*** **PASSED** The results of these Non-Clinical Bench Performance Data are provided in support of the substantial equivalence determination. ***Conclusion Supporting Substantial Equivalence:*** The results of the Software Testing conducted on the Mammotome revolve EX System demonstrates that the subject device is as safe, as effective, and performs as well as, the legally marketed predicate device. This testing supports a determination of substantial equivalence of the Mammotome revolve EX System[subject device] when compared to the Mammotome revolve Vacuum Assisted Biopsy (VAB) System device (K152989) [predicate device].
Electrical Safety and Electromagnetic Compatibilty (EMC) Testing	
• **Functional Testing** including: - Electrical Safety - Electromagnetic Compatibility ***FDA Recognized Testing Standards:*** o *IEC 60601-1:2005 + AMD1:2012 – Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.* o *IEC 60601-1-2:2014 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*	***Test Results:*** **PASSED** The results of these Non-Clinical Bench Performance Data are provided in support of the substantial equivalence determination. ***Conclusion Supporting Substantial Equivalence:*** The results of the Electrical Safety and Electromagnetic Compatibility (EMC) Testing conducted on the Mammotome revolve EX System demonstrates that the subject device is as safe, as effective, and performs as well as, the legally marketed predicate device. This testing supports a determination of substantial equivalence of the Mammotome revolve EX System [subject device] when compared to the Mammotome revolve Vacuum Assisted Biopsy (VAB) System device (K152989) [predicate device].

Animal Lab Study	
• **Tissue Sample Testing** - Sample Weight - Sample Reliability - Sample Quality ***FDA Recognized Testing Standards:*** o *GPL regulation 21 CFR Part 58*	***Test Results:*** **PASSED** The results of these Non-Clinical Bench Performance Data are provided in support of the substantial equivalence determination. ***Conclusion Supporting Substantial Equivalence:*** The results of the Animal Lab conducted on the Mammotome revolve EX System demonstrates that the subject device is as safe, as effective, and performs as well as, the legally marketed predicate device. This testing supports a determination of substantial equivalence of the Mammotome revolve EX System [subject device] when compared to the Mammotome revolve Vacuum Assisted Biopsy (VAB) System device (K152989) [predicate device].
Usability Testing	
• **Usability Testing**	***Test Results:*** **PASSED** The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence determination. ***Conclusion Supporting Substantial Equivalence:*** The results of the Usability Testing conducted on the Mammotome revolve EX System demonstrates that the subject device is as safe, as effective, and performs as well as, the legally marketed predicate device. This testing supports a determination of substantial equivalence of the Mammotome revolve EX System [subject device] when compared to the the Mammotome revolve Vacuum Assisted Biopsy (VAB) System device (K152989) [predicate device].
Conclusion: The results of the **Non-Clinical Performance Bench Testing** support the safety of the device and demonstrate that the Mammotome revolve EX System (subject device) performs as intended in the specified use conditions and comparably in terms of safety, effectiveness, and performance to the Mammotome revolve Vacuum Assisted Biopsy (VAB) System device (K152989) [predicate device] which is currently marketed for the same intended use. Therefore, this Non-Clinical Performance Bench Testing supports a determination of substantial equivalence of the Mammotome revolve EX System [subject device] when compared to the predicate device.	

Conclusion: The data generated from the results of the **Non-Clinical Performance Bench Testing** conducted on the Mammotome revolve EX System [subject device] demonstrate that the device is as safe, as effective, and performs as well as, the Mammotome revolve Vacuum Assisted Biopsy (VAB) System device (K152989) [predicate device]. Therefore, the data results may be relied on to support a determination of substantial equivalence.