DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 25, 2016

Devicor Medical Products, Inc.
Ms. Shawna Rose
Director, Regulatory Affairs
300 E-Business Way, Fifth Floor
Cincinnati, Ohio 45241

Re: K152989
Trade/Device Name: Mammotome Revolve Dual Vacuum Assist Biopsy System
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-Urology Biopsy Instrument
Regulatory Class: Class II
Product Code: KNW
Dated: November 25, 2015
Received: November 27, 2015

Dear Ms. Rose:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152989

Device Name
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® Vacuum Assisted Biopsy (VAB) 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:

Shawna Rose
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Date of Submission: November 24, 2015

Proprietary Name: Mammotome revolve® Dual Vacuum Assisted Biopsy (VAB) System

Common Name: Biopsy System

Regulation: 21 CFR 876.1075

Regulatory Class: II

Product Codes: KNW

Classification Name: Biopsy Instrument

Predicate Devices: Mammotome® Biopsy System, K033700
Mammotome revolve® Dual Vacuum Assisted Biopsy (VAB) System, K123259

Device Description: The Mammotome revolve® Dual Vacuum Assisted Biopsy (VAB) System is an electromechanical breast biopsy device indicated to provide tissue samples for diagnostic sampling of beast abnormalities for histologic examination.

The Mammotome revolve® Dual VAB 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® Dual Vacuum Assisted Biopsy (VAB) System facilitates the diagnostic removal of tissue through a combination of vacuum and rotational/translational cutting functions. The Mammotome revolve® Dual Vacuum Assisted Biopsy (VAB) System utilizes the same primary subsystems as identified in the predicate devices 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 unit, containing the vacuum pump, power supply, valve actuators, user interface touchscreen, control electronics, and software.

In addition, several optional accessories are available including remote keypad and footswitch controls, a transport cart, and probe guides for various stereotactic (ST) tables.

The Mammotome revolve® Dual VAB System has been updated to integrate the Ultrasound modality as well as improvements on the performance reliability of the stereotactic functionality, while maintaining the basic technology, functionality and clinical outcomes of the predicate systems. Consistent with the configuration of the currently marketed systems, the Mammotome revolve® VAB System is configured for use in multiple imaging modalities, including Stereotactic and Ultrasound.

The system relies on software to operate many of its functions including utilization of closed loop control on cutter position. In both predicate software systems, the focus of the software is to aid in system set-up and facilitate biopsy functions. The Mammotome revolve® Dual VAB System software has been updated to include the Ultrasound functionality, as well as to provide improved GUI screen functionality and address market feedback.

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

Side-by-Side Comparison to Legally Marketed Device

Table 1a: Capital Equipment Side-by-Side Comparison of Mammotome revolve® Holster and Control Module to previous generation Mammotome® VAB Holster and Control Modules

Device Characteristics: Holster / Control Module	Marketed Device: Mammotome® ST System (K033700)	Marketed Device: Mammotome® EX System (K033700)	Marketed Device: Mammotome revolve® (ST) Biopsy System (K123259)	Proposed Device: Mammotome revolve® (ST and U/S) Biopsy System
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	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
User interface Mechanisms	Buttons on Remote Keypad, Pedals on Footswitch, Touchscreen	Buttons on Holster, Buttons on Remote Keypad, Pedals on Footswitch, Touchscreen	Buttons on Holster, Buttons on Remote Keypad, Pedals on Footswitch, Touchscreen	Buttons on Holster, Buttons on Remote Keypad, Pedals on Footswitch, Touchscreen
Microprocessor and upgradeable software	Yes	Yes	Yes	Yes
Display	Yes, LCD display	Yes, LCD display	Yes, LCD display	Yes, LCD display
Translational Cutter Movement	Automatic or Semi Automatic	Automatic or Semi Automatic	Automatic	Automatic
Rotational Cutter Movement	Automatic with cutter advancement	Automatic with cutter advancement	Automatic with cutter advancement	Automatic with cutter advancement
Rotational and Translation Speed control	Yes; Closed-loop control	Yes; Closed-loop control	Yes, Closed loop control	Yes, Closed loop control
Drive Train Type	Flexible Mechanical Drive Cable	On board Motor and Gear Train	On board Motor and Gear Train	On board Motor and Gear Train
Independent Lateral and Axial Vacuum System	Yes	Yes	Yes	Yes
Remote Footswitch / Keypad Capability	Yes	Yes	Yes	Yes

Table 1b: Disposables Side-by-Side Comparison of Mammotome revolve® Probes to previous generation Mammotome® VAB Probes

Device Characteristics: Probes	Marketed Device: Mammotome® ST System (K033700)	Marketed Device: Mammotome® EX System (K033700)	Marketed Device: Mammotome revolve® (ST) Biopsy System (K123259)	Proposed Device: Mammotome revolve® ST and U/S Biopsy System
Needle Assembly				
Needle Insertion Method	Fired or Manual	Manual	Fired or Manual	Fired or Manual
Tip Type	Bladed trocar	Bladed trocar	Bladed trocar	Bladed trocar
Tip Material	Stainless steel	Stainless steel	Stainless steel	Stainless steel
Needle Configuration	Dual lumen	Dual lumen	Dual lumen	Dual lumen
Needle Material	Stainless steel	Stainless steel	Stainless steel	Stainless steel
Needle Diameter Sizes	8G, 11G, and 14G	8G, 11G, and 14G	8G and 10G	8G and 10G
Probe Housing				
Vacuum Port Attachment	Yes, tethered to control module	Yes, tethered to control module	Yes, tethered to Control Module	Yes, tethered to Control Module
Specimen Retrieval / Collection Method	Manual	Manual	Automatic	Automatic
Housing Material	Plastic	Plastic	Plastic	Plastic
Probe Cutter Subassembly				
Cutting Method	Rotation and translation of inner cutter	Rotation and translation of inner cutter	Rotation and translation of inner cutter	Rotation and translation of inner cutter
Tissue Transport Method	Mechanical and Vacuum	Mechanical and Vacuum	Vacuum	Vacuum
Cutter Material	Stainless steel	Stainless steel	Stainless steel	Stainless steel
Packaging				
Type	C-film with Tyvek Cover	C-film with Tyvek Cover	PETG with Tyvek Cover	PETG with Tyvek Cover
Sterilization				
Method	Cobalt 60 Irradiation	Cobalt 60 Irradiation	Cobalt 60 Irradiation	Cobalt 60 Irradiation

Performance testing:

To demonstrate substantial equivalence of the proposed device to the predicate devices, side-by-side comparison of tissue sample collection, using an in vivo porcine model, was performed. This model has historically been used to evaluate the ability of Mammotome® biopsy devices to collect tissue samples.

The Mammotome revolve® Dual Vacuum Assisted Biopsy (VAB) System and the predicate devices were each used to obtain tissue samples. Each sample was evaluated against the following criteria:

- Sample weight
- Sampling reliability
- Sample quality

Testing results confirmed that the Mammotome revolve® Vacuum Assisted Biopsy (VAB) System would retrieve a tissue sample comparable to that of the predicate device.

Additional testing was performed as well for integration of Ultrasound functionality and system enhancements. The Mammotome revolve® Dual Vacuum Assisted Biopsy (VAB) System and the predicate device were each used to obtain test functionality and obtain tissue samples. Each sample was evaluated against the following criteria:

- Sample weight
- Sampling reliability
- Sample quality
- Holster to Probe recognition
- Holster/Control Module communication

Testing results confirmed that the Mammotome revolve® Vacuum Assisted Biopsy (VAB) System Ultrasound functionality and system enhancements was comparable to that of the predicate device.

Conclusion:

Side-by-side comparison of the Mammotome revolve® Dual Vacuum Assisted Biopsy (VAB) System to the predicate systems was performed on the technical characteristics of design, product components, materials of construction, system functionality, and clinical application (specifically, tissue sample characteristics). The test results of the Mammotome revolve® Dual Vacuum Assisted Biopsy (VAB) System demonstrated that it performed comparable to the safety and effectiveness of the predicate devices, and thus can be considered substantially equivalent.