DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 5, 2016

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

Re: K161021
Trade/Device Name: HydroMARK Breast Biopsy Site Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: April 8, 2016
Received: April 12, 2016

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" (21CFR 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,

David Krause -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)*
K161021

Device Name
HydroMARK® Breast Biopsy Site Marker

Indications for Use *(Describe)*
The HydroMARK® Breast Biopsy Site Marker is indicated to mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY (21 CFR 807.92)

HYDROMARK® BREAST BIOPSY SITE MARKER

510(k) Owner: Devicor Medical Products, Inc.
300 E-Business Way, Fifth Floor
Cincinnati, Ohio 45241
Tel: 513-864-9000
Fax: 513-864-9011

Contact Person: Shawna Rose
Tel: 513-864-9178
E-mail: srose@mammotome.com

Date Prepared: April 8, 2016

Trade Name: HydroMARK® Breast Biopsy Site Marker

Common Name: Biopsy Site Marker

Classification: Class II

Classification Name: Implantable clip per 21 CFR 878.4300, NEU

Predicate Devices: Biopsy Sciences HydroMark Breast Biopsy Site Marker, K121113
Biopsy Sciences HydroMark Breast Biopsy Site Marker, K130537

Device Description: The HydroMARK® Breast Biopsy Site Marker contains a reabsorbable hydrogel component and a metallic component for permanent marking. The hydrogel has features that are unique and highly desirable for breast tissue marking.

The HydroMARK® Breast Biopsy Site Marker is provided pre-loaded in a sterile, disposable applicator that is compatible with specified commercially available biopsy devices. The HydroMARK® Breast Biopsy Site Marker is deployed by the delivery system and is left in the track created during the biopsy procedure.

This Special 510(k) is being submitted for modifications to two models of the cleared device, HydroMARK® Breast Biopsy Site Marker. The fundamental scientific technology of the two models of the modified

HydroMARK® Breast Biopsy Site Markers has not changed. This submission contains information to support:

1) Modifications to the rigid delivery system of two models of the HydroMARK® Breast Biopsy Site Marker;

2) Compatibility for use of those two models with the Mammotome revolve® biopsy system; and

3) IFU updates related to the modifications noted for those two models.

There are no changes to the supplier of the hydrogel material, or other materials of construction. There are no changes to the finished product manufacturing site. There are no changes to the sterilization location and method, no changes to packaging, no changes to shelf-life, and no changes to indications for use or intended use.

Changes to labeling include rebranding and legal manufacturer name and address, as well as updates to the IFU to incorporate instructions for use related to the added compatibility with the Mammotome revolve® Biopsy System.

Intended Use:

The indications for use and the intended use are the same for the predicate and the modified devices.

The indications for use are:

"The HydroMARK® Breast Biopsy Site Marker is indicated to mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI."

The intended use is:

"The HydroMARK® Breast Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, to be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI."

Technological Characteristics:

The hydrogel component expands on fluid contact to fill the track of the biopsy needle anchoring the marker at the exact location of biopsy.

Because the hydrogel is hydrophilic, it is clearly distinct from normal breast structure under ultrasound imaging. The hydrogel material degrades via hydrolysis over time leaving the internal stainless steel or titanium coil which provides permanent visibility under x-ray and MRI.

The modifications to the HydroMARK® Breast Biopsy Site Markers delivery system for the two models, the device compatibility testing, and the associated IFU and label changes represent minor updates to the products. The changes do not raise new questions of safety or efficacy. The technological characteristics are identical to those of the predicate devices.

Non-Clinical Performance Data: Non-clinical testing included the following:

- Visual and Dimensional Testing
- Deployment Testing
- Usability testing for ease of insertion and deployment

The devices performed as intended according to the specifications established for the finished device. The device continues to meet the ISO 10993-1 requirements for biocompatibility.

Summary of Substantial Equivalence: HydroMARK® Breast Biopsy Site Marker
Side-by-Side Comparison to Legally Marketed Device

Device Characteristics	Marketed Device HydroMARK® Breast Biopsy Site Marker	Modified Device HydroMARK® Breast Biopsy Site Marker
Indications for Use	To mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.	To mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.
Device Composition		
Marker Composition	Polymerized and desiccated hydrogel	Polymerized and desiccated hydrogel
Coil (Marker) Composition	Titanium or Stainless Steel	Titanium or Stainless Steel
Coil (Marker) Shapes	Barrel (T1) Open Coil (T3)	Barrel (T1) Open Coil (T3)

Device Characteristics	Marketed Device HydroMARK® Breast Biopsy Site Marker	Modified Device HydroMARK® Breast Biopsy Site Marker
Cannula Type	Rigid Cannula	Rigid Cannula
Cannula Material	304 Stainless Steel	304 Stainless Steel
Plunger Rod Type	Rigid Plunger Rod	Rigid Plunger Rod
Plunger Rod Material	302 Stainless Steel	302 Stainless Steel
Plunger Rod Tip	Welded Flexible Tip	Welded Spring
Packaging and Sterilization		
Sterile Packaging	Foil pouch with Tyvek® vent	Foil pouch with Tyvek® vent
Sterilization Method	ETO	ETO
Shelf Life	3 years/36 months	3 years/36 months

Conclusions: The comparison testing, including functionality, usability testing, as well as side-by-side comparison of technological characteristics of design, components and materials of construction, and clinical application, demonstrates that the two modified models of the HydroMARK® Breast Biopsy Site Markers perform as intended, accurately marking the biopsy site in the cavity of the breast biopsy. The two modified devices work in an identical manner to previously cleared HydroMARK® Breast Biopsy Site Markers. Thus, the two modified devices can be considered substantially equivalent.