April 21, 2022

Devicor Medical Products, Inc.
Diane Sung
Senior Regulatory Affairs Associate
300 E-Business Way, Fifth Floor
Cincinnati, Ohio 45241

Re: K212158
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: July 9, 2021
Received: July 12, 2021

Dear Diane Sung:

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,

for Deborah Fellhauer, RN, BSN, CQIA
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212158

Device Name
HydroMARK Breast Biopsy Site Marker

Indications for Use *(Describe)*
The HydroMARK Breast Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, including axillary lymph nodes, 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.

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510(k) Summary

I. SUBMITTER [Per 807.92(a)(1)]

Sponsor/Manufacturer

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

Contact Person

Diane Sung
Senior Regulatory Affairs Associate
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E-mail: Diane.Sung@mammotome.com

Date Prepared

July 9, 2021

II. DEVICE [Per 807.92(a)(2)]

Device Trade/Proprietary Name	**HydroMARK Breast Biopsy Site Marker**
Regulation Description	Implantable Clip
Device Common or Usual Name	Marker, Radiographic, Implantable
Device Regulatory Classification	Class II
Device Classification Regulation	21 CFR §878.4300
Product Code	(NEU) – Marker, Radiographic, Implantable
Submission Type	Traditional 510(k) Premarket Notification
Classification Panel	General & Plastic Surgery
Premarket Review	Surgical and Infection Control Devices (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)

III. PREDICATE DEVICE [Per 807.92(a)(3)]

	The Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Sponsor's own predicate devices:

Predicate Device	• **Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K210752) [predicate device]** The Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K210752) [predicate device] in terms of similar Indications for Use / Intended 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. The Devicor Medical Product, Inc. HydroMARK Breast Biopsy Site Marker (subject device) is including axillary lymph nodes to the previous Indications for Use/Intended Use statement for the direct puncture devices (4010-02-15-T1, 4010-02-15-T3, 4010-02-15-T4, 4010-02-15-S1, 4010-02-15-S3, 4010-02-18-T3). • Substantial equivalency (SE) of the subject device has also been based on substantially equivalent design, functionality, and performance characteristics as the predicate device.

IV. <u>DEVICE DESCRIPTION</u> [Per 807.92(a)(4)]

The HydroMARK Breast Biopsy Site Marker [subject device] is a two-component marker that provides permanent marking of a breast biopsy site; a resorbable hydrogel component and a metallic component, and is not intended to be removed unless the marked tissue is determined to require surgical removal. The marker is supplied pre-loaded in a sterile, disposable applicator that is compatible with specified commercially available biopsy devices.

The HydroMARK Breast Biopsy Site Marker has a resorbable component that is a highly expandable solid cylinder of polymerized and desiccated hydrogel. The hydrogel has features that are unique and highly desirable for breast tissue marking. The hydrogel material expands with fluid contact and is then resorbed by the body over time. Since the hydrogels absorb fluid, they are readily visible by ultrasound imaging. During a breast biopsy procedure, the marker is deployed through a delivery tool into the cored-out space created by a breast biopsy device. Upon expansion, the hydrogel fills the space and conforms to the site of biopsy. Embedded in the hydrogel is a coiled metallic wire made of Titanium or Stainless Steel. The wire is coiled into loops to provide a unique identifier under ultrasound, x-ray, and MRI imaging. The embedded metallic wire coil is visible under ultrasound for up to 6 weeks and is permanently visible under X-ray and MRI.

This Traditional 510(k) is being submitted for modifications to the Indications for Use/Intended Use of the cleared device, HydroMARK Breast Biopsy Site Marker (K210752) [predicate device]. The fundamental scientific technology of the HydroMARK Breast Biopsy Site Markers has not changed. 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, and no changes to shelf life.

Changes to the Indications for Use/Intended Use include modifications to the User Instructions & Operations Guide, and the Safety Information Booklet mentioned below:

- Modifying the predicate User Instructions & Operations Guide for direct puncture devices to include axillary lymph nodes in the Indications for Use statement;
- Creating a Safety Information Booklet for direct puncture devices to include axillary lymph nodes in the Indications for Use statement.

IV. INTENDED USE / INDICATIONS FOR USE [Per 807.92(a)(5)]

The Intended Use and the Indications for Use are the same for the HydroMARK Breast Biopsy Site Marker [subject device] and the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K210752) [predicate device] with the exception of the addition of axillary lymph nodes to the HydroMARK Breast Biopsy Site Marker [subject device].

[subject device]:
The HydroMARK Breast Biopsy Site Marker is intended to mark tissue during a percutaneous breast biopsy procedure, including axillary lymph nodes, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI.

[predicate device]:
The HydroMARK Breast Biopsy Site Marker is intended 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.

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE [Per 807.92(a)(6)]

The Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K210752) [predicate device] based on the same functional and performance characteristics of the subject device when compared to the predicate device. The minor differences between the subject device and predicate device User Instructions & Operation Guides, Safety Information Booklet and Intended Use/Indications for Use do not raise concerns of safety and effectiveness.

A side-by-side comparison of the technological characteristics of design, components and materials of construction between the subject device and the predicate device, as well as the minor differences in the Intended Use/Indications for Use, do not raise concerns of safety and effectiveness. The comparisons supporting a determination of substantial equivalency (SE) are provided below.

Regulatory Information	HydroMARK Breast Biopsy Site Marker [Subject Device]	HydroMARK Breast Biopsy Site Marker (K210752) [Predicate Device]	Similarities / Differences
Manufacturer	**Devicor Medical Products De Mexico S De RL De CV**	**Devicor Medical Products De Mexico S De RL De CV**	**Same**

Device Trade or Proprietary Name	**HydroMARK Breast Biopsy Site Marker**	**HydroMARK Breast Biopsy Site Marker**	**Same**
510(k) Number	N/A	K210752	**N/A**
Device Class	Class II	Class II	**Same**
Device Classification Name	Marker, Radiographic, Implantable	Marker, Radiographic, Implantable	**Same**
Device Common Name	Implantable Clip	Implantable Clip	**Same**
Product Code	(NEU) – Marker, Radiographic, Implantable	(NEU) – Marker, Radiographic, Implantable	**Same**
Regulation Number	21 CFR §878.4300	21 CFR §878.4300	**Same**
Design Features and Capabilities of the Device			
Indications for Use	To mark tissue during a percutaneous breast biopsy procedure, including axillary lymph nodes, 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.	**Different. The difference in Indications for Use (addition of axillary lymph nodes) does not raise new or different questions of safety and effectiveness. A literature review and clinician survey have been conducted to demonstrate safety and effectiveness in the axillary lymph nodes.**
Prescription or Over-the-Counter (OTC) Use	Prescription	Prescription	**Same**
Use Environment			
Sterile	Yes	Yes	**Same**
Single-Use	Yes	Yes	**Same**
Design Features			
Marker Composition	Polymerized and desiccated	Polymerized and desiccated	**Same**

	hydrogel	hydrogel	
Coil (Marker) Composition	Titanium or Stainless Steel	Titanium or Stainless Steel	**Same**
Coil (Marker) Shapes	Barrel (T1, S1) Butterfly (T4) Open Coil (T3, S3)	Barrel (T1, S1) Butterfly (T4) Open Coil (T3, S3)	**Same**
Cannula Type			
4010-02-15	Rigid	Rigid	**Same**
4010-02-18	Rigid	Rigid	**Same**
Cannula Material			
4010-02-15	Stainless Steel	Stainless Steel	**Same**
4010-02-18	Stainless Steel	Stainless Steel	**Same**
Plunger Rod Type			
4010-02-15	Rigid Stainless Steel Rod	Rigid Stainless Steel Rod	**Same**
4010-02-18	Rigid Stainless Steel Rod	Rigid Stainless Steel Rod	**Same**
Plunger Rod Material			
4010-02-15	Stainless Steel	Stainless Steel	**Same**
4010-02-18	Stainless Steel	Stainless Steel	**Same**
Packaging and Sterilization			
Packaging	Foil pouch	Foil pouch	**Same**
Sterilization Method	ETO	ETO	**Same**
Shelf Life	3 years/36 months	3 years/36 months	**Same**

VII. SUMMARY OF VERIFICATION DATA AND VERIFICATION TEST CONCLUSIONS
[Per 807.92(b)(1)(2)(3)]

Non-Clinical Bench Performance Testing was conducted on the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] to confirm that the device meets all system requirements and is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K210752) [predicate device]. The following Verification Data was 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 Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [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.	
Design Verification Analysis by Document Review	
• **Design Verification Analysis by Document Review of Labeling Changes**	***Test Results:*** **PASSED** The results of this Design Verification Analysis by Document Review were provided in support of the substantial equivalence (SE) determination.

	Conclusion Supporting Substantial Equivalence (SE): The results of the Design Verification Analysis by Document Review conducted on the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] 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 (SE) of the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] when compared to the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker (K210752) [predicate device].
Biocompatibility Testing	
• **Biocompatibility Testing** including: - Cytotoxicity - Sensitization - Irritation - Acute Systemic Toxicity - Pyrogenicity - Subchronic Toxicity - Implantation - Genotoxicity - Carcinogenicity ***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 10993-6:2016-*Biological Evaluation of Medical Devices – Part 6: Tests for local effects after implantation* 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 Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] 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 (SE) of the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] when compared to the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker (K210752) [predicate device].
Conclusion: The results of the Verification Testing support the safety of the device and demonstrate that the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] meets all design and	

functional requirements and is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K210752) [predicate device].

VIII. SUMMARY OF DESIGN VALIDATION AND CONCLUSIONS

A validation analysis was conducted on the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] to confirm the device is safe and effective for use with axillary lymph nodes and is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K210752) [predicate device]. The following Design Validation results were provided in support of the substantial equivalence (SE) determination: Literature Search and Clinician Survey.

Summary of Design Validation	
• **Literature Search**	The results of this Literature Search are provided in support of the substantial equivalence (SE) determination. ***Conclusion Supporting Substantial Equivalence:*** The results of the Literature Search conducted on the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] demonstrates that placement of the subject device in axillary lymph nodes is substantially equivalent to the predicate. All identified risks were found to be similar to risks associated with breast tissue marking and residual risks were determined to be acceptable. This Literature Search supports a determination of substantial equivalence (SE) of the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] when compared to the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K210752) [predicate device].
• **Clinician Survey**	To further reinforce the clinical use of HydroMARK Breast Biopsy Site Marker [subject device] in axillary lymph nodes, Devicor Medical Products, Inc. conducted a clinician survey of five (5) physicians to gain further insight on current practices. The five (5) clinicians provided information to support that use of the HydroMARK Breast biopsy Site Marker [subject device] in axillary lymph nodes does not raise a concern of safety or effectiveness.
Conclusion: The Design Validation results for the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] demonstrate that the subject device is as safe, and as effective as the predicate device and support a determination of substantial equivalence (SE) to the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K210752) [predicate device]. Furthermore, the Design Validation results support that using the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] to mark axillary lymph nodes demonstrates substantial equivalence.	

Summary of Literature Search:

A literature search was performed to identify, and review published scientific articles relating to the safety and effectiveness of the use of the HydroMARK Breast Biopsy Site Markers in axillary lymph nodes.

Medical journals (Google Scholar, ScienceDirect, PubMed) and the internet were searched using keywords listed below. Nineteen (19) scientific articles, with date ranges from 2015 to 2021, were found that included information about breast biopsy markers being used in the axillary lymph node area. Of these articles, sixteen (16) specifically included HydroMARK Breast Biopsy Site Markers while the other (3) three articles included other brands of markers. A total of 787 HydroMARK Breast Biopsy Site Markers were used across the 16 articles, of which 297 were used in axillary lymph nodes. Collectively, the 19 articles covered the aspects of axillary lymph node biopsy, marking, localization, surgical removal and associated risks. The adverse events identified in the literature search associated with utilizing the Biopsy Site Markers in axillary lymph nodes are similar to risks associated with using biopsy markers in breast tissue. These include clip migration and/or extrusion of the marker away from the positive lymph node, extrusion or displacement of the marker during surgical excision, difficulty in detection and visibility, ability to maintain sonographic detectability, formation of microcalcifications, failed deployment, and allergic reactions to biopsy markers. Based on the literature review, the types, severity, and frequency of adverse events as well as the performance of HydroMARK for use in axillary lymph nodes do not raise new questions of safety or effectiveness. These previously characterized risks are mitigated by the User Instructions Operations Guide. The HydroMARK product referenced in these articles is the same product as the HydroMARK Breast Biopsy Site Marker [subject device]. Therefore, the data demonstrate that the HydroMARK Breast Biopsy Site Marker [subject device] is substantially equivalent to the HydroMARK product referenced in the literature data. Therefore, these scientific literature articles support substantial equivalence of the HydroMARK Breast Biopsy Site Marker for placement in the axillary lymph nodes.

Key words:
Biopsy markers, biopsy clips, ultrasound visibility, breast ultrasound, axilla, breast cancer, contrast agents, sentinel lymph node, ultrasonography, ultrasound, clip, targeted axillary dissection, breast neoplasms, lymph nodes, magnetic resonance imaging, surgical instruments, axillary lymph node dissection, axillary staging, neoadjuvant chemotherapy, and ultrasound visibility clip.

IX. SUBSTANTIAL EQUIVALENCE SUMMARY / CONCLUSIONS

The data generated from the results of the Verification Testing, Design Validation, and clinical literature, along with a side-by-side comparison of the technological characteristics of design, components, and materials of construction between the subject device and the predicate device, demonstrate that the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] is as safe and effective and performs as well as the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K210752) [predicate device].

The similar technological and performance characteristics for the proposed Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] have been assessed to be substantially equivalent to the predicate device, and any differences in Intended Use/ Indications for Use do not raise concerns of safety and effectiveness when compared to the predicate device. Therefore, the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] is substantially equivalent to the predicate device.