April 14, 2021

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

Re: K210752
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: March 12, 2021
Received: March 15, 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,

Cindy Chowdhury -S

Cindy Chowdhury, Ph.D., M.B.A.
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)*
K210752

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, 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
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Date Prepared
March 12, 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	Special 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 (K121113) [predicate device]** • **Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K130537) [reference device]** • **Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K161021) [reference 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 (K121113) [predicate devices] and the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker (K130537 and K161021) [reference devices] in terms of the identical 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. • Substantial equivalency (SE) of the subject device has also been based on substantially equivalent design, functionality, and performance characteristics as the predicate device and reference devices.

IV. DEVICE DESCRIPTION [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 is 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 Special 510(k) is being submitted for modifications to the labeling of the cleared devices, HydroMARK Breast Biopsy Site Marker (K121113) [predicate device] and HydroMARK Breast Biopsy Site Marker (K130537 and K161021) [reference devices]. 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, no changes to shelf-life, and no changes to indications for use or intended use.

Changes to the labeling include the modifications to the User Instructions & Operations Guide, Deployment Guide, Safety and Precautions Booklet, and packaging labels mentioned below:

- Modifying the predicate User Instructions & Operations Guide from 1 summative to 7 product-based User Instructions & Operations Guides;
- Creating a Safety and Precautions Booklet, and label modifications to transition the predicate User Instructions & Operations Guide to an electronic version;
- Updating translations and symbols in the deployment guide;
- Updating labels to be more descriptive with marker shape names to match how each device is marketed, adding the manufacturing date, and changing from a barcode to a data matrix Unique Device Identifier (UDI);
- Combining package and variable labels for cost savings;
- Adding a contraindication to the predicate User Instructions & Operations Guide that the marker should not be implanted in infected areas;
- Adding a contraindication to the predicate User Instructions & Operations Guide that the physician should not use the Stainless Steel markers on patients with known nickel allergies.
    - Adding "Contains Nickel" symbols to the labels of the Stainless Steel markers.
    - Adding "Does Not Contain Nickel" symbols to the labels of the Titanium markers.
- Adding a contraindication to the predicate User Instructions & Operations Guide that the marker is not intended for the pediatric population under twelve years of age;
- Adding a contraindication to the predicate User Instructions & Operations Guide that the marker should not be used on patients with known allergies to poly (ethylene glycol), poly (trimethylene carbonate), and acrylate-capped poly (L-lactide);
- Adding an Adverse Reactions section to the predicate User Instructions & Operations Guide;
- Removing the Caution section from the predicate User Instructions & Operations Guide and transferring all the information to a new Warnings Section.
- Updating the MR Safety Information section of the predicate User Instructions & Operations Guide to include MR Image Artifact.

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 (K121113) [predicate device] and the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K130537 and K161021) [reference devices].

> *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 (K121113) [predicate device] and the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K130537 and K161021) [reference devices] based on the identical indication for use / intended use and the same functional and performance characteristics of the subject device when compared to the predicate device and the reference devices. The minor differences between the subject device and predicate device/reference devices User Instructions & Operation Guides and labeling do not raise new or different issues 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/reference devices, as well as, the minor differences in the User Instructions & Operation Guide and labels which do not raise new or different issues of safety and effectiveness, support a determination of substantial equivalency (SE) is provided below.

Regulatory Information	**HydroMARK Breast Biopsy Site Marker [Subject Device]**	**HydroMARK Breast Biopsy Site Marker (K121113) [Predicate Device]** **HydroMARK Breast Biopsy Site Marker (K130537 and K161021) [Reference Devices]**	**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	K121113 K130537 K161021	**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, 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.	**Same**
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 hydrogel	Polymerized and desiccated hydrogel	**Same**
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			
4010-01-08	Flexible	Flexible	**Same**
4010-03-09	Rigid	Rigid	**Same**
4010-04-09	Rigid	Rigid	**Same**
4010-01-11	Rigid	Rigid	**Same**
4010-02-15	Rigid	Rigid	**Same**
4010-03-15	Rigid	Rigid	**Same**
4010-02-18	Rigid	Rigid	**Same**
Cannula Material			
4010-01-08	Polyether-b-amide	Polyether-b-amide	**Same**
4010-03-09	Stainless Steel	Stainless Steel	**Same**
4010-04-09	Stainless Steel	Stainless Steel	**Same**
4010-01-11	Polyether-b-amide	Polyether-b-amide	**Same**
4010-02-15	Stainless Steel	Stainless Steel	**Same**
4010-03-15	Stainless Steel	Stainless Steel	**Same**
4010-02-18	Stainless Steel	Stainless Steel	**Same**
Plunger Rod Type			
4010-01-08	Continuous Flexible Nylon Rod	Continuous Flexible Nylon Rod	**Same**
4010-03-09	Rigid Stainless Steel Rod with welded Flexible Spring Tip	Rigid Stainless Steel Rod with welded Flexible Spring Tip	**Same**

4010-04-09	Rigid Stainless Steel Rod	Rigid Stainless Steel Rod	**Same**
4010-01-11	Continuous Flexible Nylon Rod	Continuous Flexible Nylon Rod	**Same**
4010-02-15	Rigid Stainless Steel Rod	Rigid Stainless Steel Rod	**Same**
4010-03-15	Rigid Stainless Steel Rod	Rigid Stainless Steel Rod	**Same**
4010-02-18	Rigid Stainless Steel Rod	Rigid Stainless Steel Rod	**Same**
Plunger Rod Material			
4010-01-08	Nylon	Nylon	**Same**
4010-03-09	Stainless Steel Rod + Stainless Steel Tension Spring Flexible Tip	Stainless Steel Rod + Stainless Steel Tension Spring Flexible Tip	**Same**
4010-04-09	Stainless Steel	Stainless Steel	**Same**
4010-01-11	Nylon	Nylon	**Same**
4010-02-15	Stainless Steel	Stainless Steel	**Same**
4010-03-15	Stainless Steel	Stainless Steel	**Same**
4010-02-18	Stainless Steel	Stainless Steel	**Same**
Packaging and Sterilization			
Packaging	Foil pouch with Tyvek vent	Foil pouch with Tyvek vent	**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)]

Verification Testing by document analysis of the labeling modifications was conducted on the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] to confirm that the device meets all system labeling requirements and is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K121113) [predicate device] and the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K130537 and K161021) [reference devices]. The following Verification Data was provided in support of the substantial equivalence (SE) determination.

Verification Testing

- **Verification Testing** including:
  - **Document Analysis of Labeling Changes**

Summary of Non-Clinical Bench Performance Testing	
• **Design Verification by Document Analysis of Labeling Changes** ***FDA Recognized Testing Standards:*** ○ ISO 13485:2016 Certification –	***Test Results:*** **PASSED** The results of these Verification Data are provided in support of the substantial equivalence (SE) determination.

Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes *process for medical devices* ○ ISO 14971:2007 (Ed.2.0) - Medical Devices - Application of Risk Management to Medical Devices	***Conclusion Supporting Substantial Equivalence:*** The results of the Design Verification Testing by Document Analysis of Labeling Changes conducted on the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] demonstrates that the subject device is as safe and as effective as the legally marketed predicate device and reference devices. This testing supports a determination of substantial equivalence 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 (K121113) [predicate device] and the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K130537 and K161021) [reference devices].
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 (K121113) [predicate device] and the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K130537 and K161021) [reference devices].	

VIII. CONCLUSIONS

The data generated from the results of the Verification Testing 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/reference devices 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 (K121113) [predicate device] and the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K130537 and K161021) [reference devices].

The similar indications for use, intended use, technological characteristics, 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/reference devices, and any differences in labeling do not raise different issues of safety and effectiveness when compared to the predicate and reference devices. Therefore, the Devicor Medical Products, Inc. HydroMARK Breast Biopsy Site Marker [subject device] is substantially equivalent to the predicate and reference devices.