



July 10, 2024

Devicor Medical Products, Inc.
Katy Austin
Senior Regulatory Affairs Specialist
300 E-Business Way, Fifth Floor
Cincinnati, Ohio 45241

Re: K240527

Trade/Device Name: HydroMARK™ Plus Breast Biopsy Site Marker (Hummingbird Shape) (4010-02-15-T6)

Regulation Number: 21 CFR 878.4300

Regulation Name: Marker, Radiographic, Implantable

Regulatory Class: Class II

Product Code: NEU

Dated: June 10, 2024

Received: June 11, 2024

Dear Katy Austin:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tek N. Lamichhane -S

Digitally signed by Tek N.
Lamichhane -S
Date: 2024.07.10 20:36:18 -04'00'

Tek Lamichhane, Ph.D.

Assistant Director

DHT4B: Division of Infection Control

and Plastic and Reconstructive Surgery Devices

OHT4: Office of Surgical and Infection Control Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K240527

Device Name

HydroMARK™ Plus Breast Biopsy Site Marker (Hummingbird Shape) (4010-02-15-T6)

Indications for Use (Describe)

The HydroMARK™ Plus Breast Biopsy Site Marker is indicated to mark tissue during a percutaneous breast biopsy procedure, including axillary lymph nodes, be visible under ultrasound for at least six (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.

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510(k) Summary K240527

SUBMITTER

Sponsor/Manufacturer

Devicor Medical Products, Inc.
300 E. Business Way, Fifth Floor
Cincinnati, OH 45241 U.S.A.

Establishment Registration Number

3008492462

Official Correspondent for Devicor Medical Products, Inc.

Katy Austin, Senior Regulatory Affairs Specialist

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Date Prepared

July 8, 2024

DEVICE

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

PREDICATE DEVICE

Predicate Device	The Devicor Medical Products, Inc. HydroMARK™ Plus Breast Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Sponsor's own predicate devices: • Devicor Medical Products Inc. HydroMARK™ Plus Breast Biopsy Site Marker (K221961) [Dragonfly, predicate device] The Devicor Medical Products, Inc. HydroMARK™ Plus Breast Biopsy Site Marker [Hummingbird, subject device] is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK™ Plus Breast Biopsy Site Marker (K221961) [Dragonfly, predicate device] in terms of identical Indications for Use / Intended Use.
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	The HydroMARK™ Plus Breast Biopsy Site Marker is indicated to mark tissue during a percutaneous breast biopsy procedure, including axillary lymph nodes, be visible under ultrasound for at least six (6) weeks, and be permanently visible by x-ray and MRI. Substantial equivalence (SE) of the subject device is based on substantially equivalent design, functionality, and performance characteristics as the predicate device.
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DEVICE DESCRIPTION

The HydroMARK™ Plus Breast Biopsy Site Marker (Hummingbird, subject device) is a two-component marker that provides permanent marking of a breast biopsy or axillary lymph node biopsy site following a breast biopsy procedure. The implantable marker is made of a highly expandable solid cylinder of polymerized and desiccated hydrogel that has the permanent titanium marker embedded. Upon fluid contact (e.g., water, blood, etc.), the hydrogel material expands to an equilibrium point. Once the material hydrates, it is visible under ultrasound. Over time, the hydrogel is resorbed by the patient's body. The titanium wire is permanently visible under x-ray and MRI even after the hydrogel is resorbed.

The HydroMARK™ Plus Breast Biopsy Site Marker is a permanent implant and is not intended to be removed unless the marked tissue requires surgical removal. The marker is supplied pre-loaded in a sterile, disposable applicator that is designed to fit into specified commercially available breast biopsy devices. During a breast biopsy procedure, the marker is deployed through a compatible introducer or by direct puncture into the biopsy cavity created by the breast biopsy device.

Model Number	Material	Shape type	Shape
4010-02-15-T6	Titanium	Hummingbird	

This Traditional 510(k) is being submitted to introduce HydroMARK™ Plus Breast Biopsy Site Markers to the marketplace as part of the Mammotome brand, and the fundamental scientific technology when compared to the HydroMARK™ Plus Breast Biopsy Site Marker (K221961) [Dragonfly, predicate device] has not changed. HydroMARK™ Plus Breast Biopsy Site Marker [Hummingbird, subject device] will have an 18 month shelf life at launch.

A User Instructions & Operations Guide, and Safety Information Booklet will be provided for all HydroMARK™ Plus Breast Biopsy Site Markers.

INDICATIONS FOR USE

The HydroMARK™ Plus Breast Biopsy Site Marker is indicated to mark tissue during a percutaneous breast biopsy procedure, including axillary lymph nodes, be visible under ultrasound for at least six (6) weeks, and be permanently visible by x-ray and MRI.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Devicor Medical Products, Inc. HydroMARK™ Plus Breast Biopsy Siter Marker [Hummingbird, subject device] is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK™ Plus Breast Biopsy Site Marker (K221961) [Dragonfly, predicate device] based on the similar functional and performance characteristics of the subject device when compared to the predicate device. The minor differences between the subject device and predicate device regarding marker shape do not raise concerns of safety and effectiveness.

A side-by-side comparison of the technological characteristics of the subject device and the predicate device, supports a determination of substantial equivalency (SE) per the table below.

<i>Subject HydroMARK™ Plus Comparison to Predicate HydroMARK™ Plus (K221961)</i>			
<i>Regulatory Information</i>	HydroMARK™ Plus Breast Biopsy Site Marker [Hummingbird, Subject Device] K240527	HydroMARK™ Plus Breast Biopsy Site Marker [Dragonfly, Predicate Device] K212158	Comparison
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™ Plus Breast Biopsy Site Marker	HydroMARK™ Plus Breast Biopsy Site Marker	Same
Device Class	Class II	Class II	Same
Device Classification Name	Marker, Radiographic, Implantable	Marker, Radiographic, Implantable	Same
Device Common Name	Implantable Marker	Implantable Marker	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, including axillary lymph nodes, 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 Material	Titanium marker, surrounded by hydrogel	Titanium marker, surrounded by hydrogel	Same
Marker Shape	Hummingbird	Dragonfly	Substantially Equivalent
Cannula Type	Rigid	Rigid	Same
Cannula Material	Stainless Steel	Stainless Steel	Same
Plunger Rod Material	Stainless Steel	Stainless Steel	Same
Plastic Handle	Plastic Polymer	Plastic Polymer	Same
Plunger Lock	Plastic Polymer	Plastic Polymer	Same
Plastic Plunger Button	Plastic Polymer	Plastic Polymer	Same
Shelf Life	1.5 years/18 months	1.5 years/18 months	Same
Biocompatibility results	- Chemical Characterization - Cytotoxicity - Sensitization - Irritation - Acute Systemic Toxicity - Pyrogenicity - Subacute/ Chronic/ Subchronic Toxicity - Implantation - Genotoxicity - Carcinogenicity	- Chemical Characterization - Cytotoxicity - Sensitization - Irritation - Acute Systemic Toxicity - Pyrogenicity - Subacute/ Chronic/ Subchronic Toxicity - Implantation - Genotoxicity - Carcinogenicity	Same
Performance evaluation testing	- Marker Size - Deployment Force - Visibility	- Marker Size - Deployment Force - Visibility	Substantially Equivalent
MR Testing Results			
MR Status for Marker	MR Conditional	MR Conditional	Same
MR Status for Applicator	MR Unsafe	MR Unsafe	Same

SUMMARY OF VERIFICATION DATA AND VERIFICATION TEST CONCLUSIONS

Summary of Performance Testing	
Performance Testing was conducted on the Devicor Medical Products, Inc. HydroMARK™ Plus 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 (K221961) [predicate device]. The following Verification Data was provided in support of the substantial equivalence (SE) determination.	
Performance Testing	
<u>Performance Testing HydroMARK™ Plus</u>	<u>Test Results: PASSED</u> The results of all performance testing met acceptance criteria and are provided in support of the substantial equivalence determination.
<u>HydroMARK™ Plus Risk Management</u>	<u>Results:</u> All risks have been reduced as far as possible through allowed controls: Inherent safety by design, information for safety, and/or preventative measures.
<u>FDA Recognized Testing Standards:</u> - ISO 13485:2016 Certification – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes process for medical devices - ISO 14971:2019 (Ed.3.0) – Medical Devices - Application of Risk Management to Medical Devices	<u>Conclusion Supporting Substantial Equivalence:</u> The results of the design verification carried out within Devicor Medical Product’s ISO 13485:2016 compliant Quality Management System conducted on the HydroMARK™ Plus Breast Biopsy Site Marker [subject device] demonstrates that the subject device is as safe and as effective as the legally marketed predicate device. This evidence in conjunction with the ISO 14971:2019 compliant Risk Management process supports a determination of substantial equivalence of the Devicor Medical Products, Inc. HydroMARK™ Plus Breast Biopsy Site Marker [Hummingbird, subject device] when compared to the Devicor Medical Products Inc. HydroMARK™ Plus Breast Biopsy Site Marker (K221961) [Dragonfly, predicate device].
Biocompatibility Testing	
<u>Biocompatibility Testing</u> including: - Chemical Characterization - Cytotoxicity - Sensitization - Irritation - Acute Systemic Toxicity - Material-Mediated Pyrogenicity - Subacute/Subchronic/ Chronic Toxicity - Implantation Effects - Genotoxicity - Carcinogenicity	<u>Test Results: PASSED</u> The results of these Non-Clinical Bench Performance Data are provided in support of the substantial equivalence determination.

<u>FDA Recognized Testing Standards:</u> • <i>ISO 10993-1:2018-Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process</i> • <i>ISO 10993-3:2014 Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity</i> • <i>ISO 10993-5:2009-Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity</i> • <i>ISO 10993-6:2016-Biological Evaluation of Medical Devices – Part 6: Tests for local effects after implantation</i> • <i>ISO 10993-10:2010-Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization</i> • <i>ISO 10993-11:2017-Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity</i> • <i>ISO 10993-17:2002 Biological Evaluation of Medical Devices – Part 17: Establishment of allowable limits for leachable substances</i> • <i>ISO 10993-18:2020 Biological Evaluation of Medical Devices – Part 18: Chemical characterization of medical device materials within a risk management process</i> • <i>ISO 10993-23:2021 Biological Evaluation of Medical Devices – Part 23: Tests for Irritation</i>	<u>Conclusion Supporting Substantial Equivalence:</u> The results of the Biocompatibility Testing conducted on the Devicor Medical Products, Inc. HydroMARK™ Plus Breast Biopsy Site Marker [Hummingbird, 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™ Plus Breast Biopsy Site Marker [Hummingbird, subject device] when compared to the Devicor Medical Products, Inc. HydroMARK™ Plus Breast Biopsy Site Marker (K221961) [Dragonfly, predicate device].
<u>Conclusion:</u> The results of the Verification Testing support the safety of the device and demonstrate that the Devicor Medical Products, Inc. HydroMARK™ Plus Breast Biopsy Site Marker [Hummingbird, subject device] meets all design and functional requirements and is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK™ Plus Breast Biopsy Site Marker (K221961) [Dragonfly, predicate device].	

SUBSTANTIAL EQUIVALENCE SUMMARY / CONCLUSIONS

Based on the verification results and a side-by-side comparison of the technological characteristics of design, indication for use / intended use, components, and materials of construction, it is concluded that the Devicor Medical Products, Inc. HydroMARK™ Plus Breast Biopsy Site Marker [Hummingbird, subject device] is substantially equivalent to the Devicor Medical Products Inc. HydroMARK™ Plus Breast Biopsy Site Marker (K221961) [Dragonfly predicate devices].