January 23, 2026

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

Re: K253761
Trade/Device Name: HydroMARK™ Plus Breast Biopsy Site Marker (Dragonfly Shape);
HydroMARK™ Plus Breast Biopsy Site Marker (Hummingbird Shape)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: November 25, 2025
Received: November 25, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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
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Tek N. 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

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)*
K253761

Device Name
HydroMARK™ Plus Breast Biopsy Site Marker(Dragonfly and Hummingbird)

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.

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:

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510(k) Summary
(K253761)

As required by the Safe Medical Devices Act of 1990, coded under Section 513, Part (I)(3)(A) of the Food, Drug and Cosmetic Act, a summary of the information upon which substantial equivalence determination is based on is as follows:

1. Submitter Information:

Applicant: Devicor Medical Products, Inc.
300 E-Business Way, Fifth Floor
Cincinnati, OH 45242
Contact: Katy Austin, Principal Regulatory Affairs
Phone: 513-708-6267
Email: katy.austin@mammotome.com

Date: November 25, 2025

2. Subject Device:

Device Trade Name: HydroMARK™ Plus Breast Biopsy Site Marker(Dragonfly and Hummingbird)
Classification Name: Marker, Radiographic, Implantable (Product Code: NEU)
Review Panel: General & Plastic Surgery
Regulation Number: 21 CFR §878.4300

3. Predicate Device:

HydroMARK™ Plus Breast Biopsy Site Marker(Dragonfly, K221961)

4. Reference Device:

HydroMARK™ Plus Breast Biopsy Site Marker(Hummingbird, K240527)

5. Device Description:

The HydroMARK™ Plus Breast Biopsy Site Marker (Dragonfly and Hummingbird shapes) 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 into the biopsy cavity created by the breast biopsy device.

The focus of this submission is a modification to the applicator of the marker, which has been modified to enhance compatibility of use in the MR Environment. The markers themselves remain unchanged from the predicate device.

6. Indications for Use of Device:

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.

7. Technological Comparison to Predicate Device:

The technological characteristics of the subject device are substantially equivalent to those of the predicate device, in terms of following:

- Intended Use
- Indications for Use
- Performance Characteristics
- Target Population
- Fundamental Scientific Technology
- Mechanism of Action
- Marker Material
- Sterility Assurance and Method of Sterilization
- Shelf-Life
- Packaging Configuration

The subject device and the predicate device are different in the following manner:

- Stainless steel materials
- Biopsy method (MRI imaging versus ultrasound)
- Plastic colorants

8. Performance Testing Summary:

To demonstrate substantial equivalence of the subject device to the predicate device, the technological characteristics and performance criteria were evaluated. Using the FDA Guidance document, “Design Control Guidance for Medical Device Manufacturers,” dated March 11, 1997, and internal risk assessments procedures, the following non-clinical tests were performed:

- Marker Deployment Accuracy
- Marker Deployment Force
- Marker Size (width)
- Human Factors Engineering Testing
- Usability
- Magnetic Resonance Safety
- Biocompatibility Testing

Performance Testing	
Performance Testing HydroMARK™ Plus	*Test Results:* PASSED
Biocompatibility Testing	
Cytotoxicity Sensitization Irritation Acute Systemic Toxicity Material-Mediated Pyrogenicity	*Test Results: PASSED*

The biologic test results demonstrate that the subject device is biocompatible for its intended use. The technological characteristics and performance criteria of the HydroMARK Plus™ Breast Biopsy Site Marker (Dragonfly and Hummingbird) are comparable to the predicate device and that they perform as safely and as effectively as the legally marketed predicate device.

9. Conclusion:

The HydroMARK Plus™ Breast Biopsy Site Marker (Dragonfly and Hummingbird) are substantially equivalent to the legally marketed predicate device, the HydroMARK Plus™ Breast Biopsy Site Marker (Dragonfly: K221961).