August 31, 2023

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

Re: K221961
Trade/Device Name: HydroMARK Plus Breast Biopsy Site Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU

Dear Katy Austin:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter 07/13/2023. Specifically, FDA is updating this SE Letter with the correct IFU in the 510K database as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Tek Lamichhane, OHT4: Office of Surgical and Infection Control Devices, **301-796-8983**, **tek.lamichhane@fda.hhs.gov**.

Sincerely,

Tek N. Lamichhane -S
Digitally signed by Tek N. Lamichhane -S
Date: 2023.08.31 15:34:24 -04'00'

Tek N. Lamichhane, Ph.D.
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

July 13, 2023

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

Re: K221961
Trade/Device Name: HydroMARK Plus Breast Biopsy Site Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: April 27, 2023
Received: April 27, 2023

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 (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,

David Krause -S

David Krause, Ph.D.
Deputy Director,
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)*
K221961

Device Name
HydroMARK Plus Breast Biopsy Site Marker

Indications for Use *(Describe)*
HydroMARK™ Plus 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.**

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.***

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*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

## 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

Katy Austin
Regulatory Affairs Specialist
Devicor Medical Products, Inc.
300 E-Business Way, Fifth Floor
Cincinnati, OH 45241
Ph: +1-513-708-6267
E-mail: katy.austin@mammotome.com

### Date Prepared

July 11, 2023

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

| | |
|---|---|
| *Device Trade/Proprietary Name:* | HydroMARK™ Plus Breast Biopsy Site Marker |
| *Device Common or Usual Name:* | Implantable Marker |
| *Device Classification Name:* | Marker, Radiographic, Implantable |
| *Device Regulatory Classification:* | Class II |
| *Device Classification Regulation:* | 21 CFR §878.4300 |
| *Product Code:* | (NEU) Marker, Radiographic, Implantable |
| *Submission Type:* | Premarket Notification Traditional 510(k) Submission |
| *Review Panel:* | General & Plastic Surgery |
| *Premarket Review:* | Surgical and Infection Control Devices (OHT4)<br>Division of Health Technology 4B (DHT4B) |

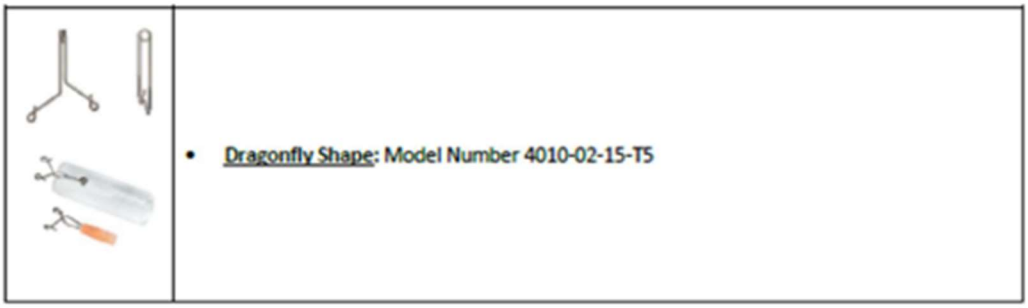
## III. PREDICATE DEVICE [Per 807.92(a)(3)]

| | |
|---|---|
| **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:<br><br>• **Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate devices]**<br><br>The Devicor Medical Products, Inc. HydroMARK™ Plus Breast Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate devices] in terms of the identical indications for use / intended use to mark tissue during a percutaneous breast biopsy procedure, including axillary lymph nodes, being visible under ultrasound for at least 6 weeks, and being permanently visible by x-ray and MRI.<br><br>• Substantial equivalency (SE) of the subject device has also been based on substantially equivalent design, functionality, and performance characteristics compared to the predicate device. |

## IV. DEVICE DESCRIPTION [Per 807.92(a)(4)]

The HydroMARK™ Plus Breast Biopsy Site Marker contains a two-component implantable 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 implantable marker is not intended to be removed unless the marked tissue requires surgical removal.

The implantable component of the HydroMARK™ Plus Biopsy Site 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.



- Dragonfly Shape: Model Number 4010-02-15-T5

This Traditional 510(k) is being submitted to add a new marker device to the HydroMARK™ product line (K212158) [predicate device] that has an additional shape (named "Dragonfly") of the embedded titanium wire coil in the hydrogel. The fundamental scientific technology of the HydroMARK™ Plus Breast Biopsy Site Marker [subject device] has not changed compared to the HydroMARK™ Breast Biopsy Site Marker [predicate device]. This submission contains information to support:

- Modifying the titanium wire shape to reflect the additional marker shape of Dragonfly under this HydroMARK™ Plus Breast Biopsy Site Marker [subject] submission.
- Slight modification to the length of the hydrogel (shorter) than the other 4010-02-15 product codes
- Full product dimensions for subject device were provided in figure and tabular format
- Slight modification to the packaging configuration versus the other 4010-02-15 product codes have been made including a change in supplier
- Slight modification in package dimensions reducing the overall length and width of the pouch from 22.5" x 6.125" to 21.5 x 4.5".
- Minor modifications to the product pouch folder including reducing the width of the folder and assembled length and reducing the length of the protective sheath.
- New User Instructions & Operations Guide providing guidance for safe and effective use of HydroMARK™ Plus, including MRI information and safety clarifications
- New Safety Information Booklet has been provided with updates reflecting the new marker device shape including MRI information and safety clarifications

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, changes to packaging are minor including a smaller foil pouch with a new supplier (additional information on Sterilization, Shelf-Life and Packaging may be found in e-copy **VOL_004_STERILE-SL-PKG**), and no changes to indications for use or intended use.

The shelf life for HydroMARK™ Plus Breast Biopsy Site Mark [subject device] will be 18 months, whereas the HydroMARK™ Breast Biopsy Site Marker [predicate device] is sold with a 3 year shelf life. At the time of this submission, we are still awaiting device performance data for the 36 month time point for the Dragonfly 4010-02-15-T5 HydroMARK™ Plus medical device.

Please refer to the table below for additional details on the design and use of the device.

| Design and Use of the Device | Yes | No |
|---|---|---|
| Is the device intended for prescription use (21 CFR 801 Subpart D)? | X | |
| Is the device intended for over-the-counter use (21 CFR 807 Subpart C)? | | X |
| Does the device contain components derived from a tissue or other biologic source? | | X |
| Is the device provided sterile? [Probes and Introducers Only] | X | |
| Is the device intended for single use? [Probes and Introducers Only] | X | |
| Is the device a reprocessed single use device? | | X |
| If yes, does this device type require reprocessed validation data? | | X |
| Does the device contain a drug? | | X |
| Does the device contain a biologic? | | X |
| Does the device use software? | | X |
| Does the submission include clinical information? | | X |
| Is the device implanted? | X | |

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

The intended use and the indications for use are the same for the HydroMARK™ Plus Breast Biopsy Site Marker [subject device] and the Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate devices].

The HydroMARK™ Plus 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.

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

The Devicor Medical Products, Inc. HydroMARK™ Plus Breast Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate 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.

The HydroMARK™ Plus Biopsy Site Marker Implant Component and Applicator System of the medical device in its final finished form are comprised of identical materials for the implant components and the same applicator system of the currently marketed Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K212158) [predicate device]. The HydroMARK™ Plus Biopsy Site Marker is identical in formulation, processing, sterilization, and chemicals (e.g., no additional plasticizers, fillers, additives, cleaning agents, mold release agents in subject device).

As shown below, a side-by-side comparison of the technological characteristics of between the subject device and the predicate devices, do not raise new or different issues of safety and effectiveness, support a determination of substantial equivalency (SE).

| Regulatory Information | HydroMARK™ Plus Breast Biopsy Site Marker (K221961) [Subject Device] | HydroMARK™ Breast Biopsy Site Marker (K212158) [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™ Plus Breast Biopsy Site Marker | HydroMARK™ Breast Biopsy Site Marker | **Different - Minor**<br><br>**Brand clarifier of "Plus" creates no concerns of safety or efficacy** |
| **510(k) Number** | K221961 | K212158 | **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, 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 Composition** | Polymerized and desiccated hydrogel | Polymerized and desiccated hydrogel | **Same** |
| **Coil (Marker) Composition** | Titanium | Titanium or Stainless Steel | **Same as the Titanium HydroMARK™ offerings** |
| **Coil (Marker) Shapes** | Dragonfly (T5) | Barrel (T1, S1) Butterfly (T4) Open Coil (T3, S3) | **Different shape, no impact to safety or efficacy** |
| **Cannula Type** | | | |
| **4010-02-15** | Rigid | Rigid | **Same** |
| **Cannula Material** | | | |
| **4010-02-15** | 304 Stainless Steel | 304 Stainless Steel | **Same** |
| **Plunger Rod Type** | | | |
| **4010-02-15** | Rigid Stainless Steel Rod | Rigid Stainless Steel Rod | **Same** |
| **Packaging and Sterilization** | | | |
| **Packaging** | Smaller foil pouch with Tyvek vent | Foil pouch with Tyvek vent | **Same just smaller, no impact to safety or efficacy** |
| **Sterilization Method** | ETO | ETO | **Same** |
| **Shelf Life** | 1.5 years/18 months | 3 years/36 months | **Shorter shelf life, no impact to safety or efficacy** |
| **MRI Status** | | | |
| **MRI Status (Marker)** | Conditional | Conditional | **Same** |
| **MRI Status (Applicator)** | Unsafe | Unsafe | **Same** |

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

Verification Testing is summarized in the table below.

| *Summary of Non-Clinical Performance Testing* | |
|---|---|
| **Performance Testing HydroMARK™ Plus vs. HydroMARK™** | ***Test results:*** **PASSED**<br>The results of the Non-Clinical Bench Performance Data are provided in support of the substantial equivalence determination.<br><br>***Conclusion Supporting Substantial Equivalence:***<br>The results of Non-Clinical Bench Performance Data conducted on the HydroMARK™ Plus Biopsy Site Marker 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 of the HydroMARK™ Plus Biopsy Site Marker [subject device] when compared with the HydroMARK™ Biopsy Site Marker [predicate device]. |
| **Provision of Data to Demonstrate Safety and Effectiveness of Subject Device** | ***RESULTS:*** Both immediate post-deployment testing and long-term migration performance of HydroMARK Plus Breast Biopsy Site Markers were confirmed. |
| **Provision of Support Demonstrating Safety and Effectiveness for HydroMARK™ Plus implantation** | ***RESULTS:*** Literature analysis was provided demonstrating product is safe and effective in both breast and lymph node. |
| **Performance Testing: Residual Moisture** | ***RESULTS:*** Testing provided no statistical difference with 95% confidence comparing predicate and subject devices, proving substantial equivalence. |
| **Performance Testing: Hydrogel Degradation** | ***RESULTS:*** Testing and existing clinical evidence of HydroMARK™ hydrogel was provided demonstrating substantial equivalence between predicate and subject devices. |
| **Performance Testing: Time to Equilibrium** | ***RESULTS:*** Testing proved both subject and predicate devices achieved hydrogel equilibrium within 24 hours, demonstrating substantial equivalence. |
| *Summary of Biocompatibility Testing* | |
| **Biological Evaluation Testing** | ***Test Results: PASSED***<br>All the biocompatibility testing conducted on the HydroMARK™ device is applicable to HydroMARK™ Plus devices as well since it is an extension of the existing HydroMARK™ product family and does not serve as a new worst-case. Hence, no additional biocompatibility tests were conducted except for the implantation study for 8 weeks timepoint in order to assess the local tissue effects due to the exposed region of the marker. The materials utilized in the HydroMARK™ and HydroMARK™ Plus Biopsy Site Marker devices have been evaluated against all applicable biological endpoints and are considered biocompatible in accordance with EN ISO 10993-1:2020 – Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process. |

| | |
|---|---|
| **Acute Systemic Toxicity** | ***Results: PASSED***<br>All tests passed per ISO 10993-11:2017. There was no mortality during the studies of the implant and delivery device. All animals were clinically normal throughout both studies. Body weight data was acceptable. Each test article met the requirements of the study. |
| **HydroMARK™ Implantation Data** | ***Results: PASSED***<br>All tests passed and no local tissue side effects were observed at both lymph node and intramuscular sites at 8 and 26 weeks. Applies only to implant portion of the device. |
| **HydroMARK™ Plus Implantation Data** | ***Results: PASSED***<br>All animals survived, and no abnormalities or adverse reactions were observed at necroscopy. Overall, the test article scored a relative score of "0" with a reactivity grade of "minimal or no reaction" per Table E.3. of ISO 10993-6:2016 and met the requirements of the study. |
| **HydroMARK™ Cytotoxicity Data** | ***Results:*** The test article extract met the requirements of the test since the grade was less than a grade 2 (mild reactivity) in each test and passed per ISO 10993-5:2009 |
| **HydroMARK™ Biocompatibility Chemical Analysis** | ***Results:*** The toxicological analysis shows a margin of safety greater for the chemicals and based on the analysis, they are considered acceptable. Subacute/Subchronic/Chronic Toxicity/Carcinogenicity/ Genotoxicity/Reproductive Toxicity – No additional tests were conducted based on the toxicological analysis which showed the risk to be acceptable in adult women. |

| | |
|---|---|
| **HydroMARK™ Irritation Data** | ***Results:*** The difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.0 for the polar and non-polar test article extracts, respectively, for both the implant and delivery device. Each test article met the requirements of the test per ISO 10993-10:2010. |
| **HydroMARK™ Sensitization Data** | ***Results:*** The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig for either the implant or delivery device. The test article was not considered a sensitizer in the guinea pig maximization tests and met the requirements of the test per ISO 10993-10:2010. |
| **HydroMARK™ Pyrogenicity Data** | ***Results:*** No single animal showed a temperature rise of 0.5°C or more above its baseline temperature. The total temperature rise during 3 hours was 0.1°C for the implant and 0.3°C for the delivery device. Each test article met the requirements for the absence of pyrogens per ISO 10993-11:2017. |
| **Materials Assessment and Plan** | ***Results:*** The manufacturing process along with the packaging materials and the sterilization process is very similar for both HydroMARK™ and HydroMARK™ Plus. However, considering the geometry and design of the marker for HydroMARK™ Plus, a portion of the marker is exposed from the hydrogel. Therefore, an additional implantation study was performed to assess the local tissue effects of the implant component materials due to new marker configuration outside of gel when implanted. The implantation data on file for the HydroMARK™ device includes both the standard muscle implantation and lymph node sites and were used to supplement the additional implantation study. The implantation time point for assessment was based on the degradation profile of the device and historical data on the hydrogel material.<br>The primary implantation assessment was completed at 8 weeks. Additional implantation data at 26 weeks (steady state) following implantation is found in PCR-000237 (HydroMARK™ Implantation Data GLP 26 wks) considering the similarity between the HydroMARK™ and HydroMARK™ Plus markers. |

| | |
|---|---|
| ***FDA Recognized Testing Standards for biocompatibility:***<br>○ *ISO 10993-1:2018-Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*<br>○ *ISO 10993-5:2009-Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity*<br>○ *ISO 10993-6:2016-Biological Evaluation of Medical Devices – Part 6: Tests for local effects after implantation*<br>○ *ISO 10993-10:2010-Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization*<br>○ *ISO 10993-11:2017-Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity*<br>○ *ISO 10993-12:2012-Biological Evaluation of Medical Devices – Part 12: Sample preparation and reference materials.* | ***Conclusion (Biocompatibility Testing Standards) Supporting Substantial Equivalence:***<br><br>The data generated from the results of the Biocompatibility Testing (GLP Cytotoxicity, GLP Sensitization, GLP Irritation, GLP Acute Systemic Toxicity, GLP Pyrogenicity, GLP Implantation, and chemical characterization) performed on the Devicor Medical Products, Inc. HydroMARK™ and HydroMARK™ Plus Breast Biopsy Site Marker [subject device] and the rationale to use existing biocompatibility test results for many of the biological endpoints demonstrate that the subject device is as safe, as effective, and performs as well as the predicate device, and meets the requirements of EN ISO 10993-1:2020.<br><br>Therefore, the information provided may be relied on to support a determination of substantial equivalence (SE). |
| ***Risk Management*** | |
| **HydroMARK™ Risk Management Report** | ***Results:*** All risks have been reduced as far as possible through allowed controls. The results of the Risk Management Report are provided in support of the substantial equivalence determination.<br>• The product risk is acceptable in view of the benefits of the device. |
| **HydroMARK™ System FMEA** | ***Results:*** Based on the clinical steps and failure modes tested on HydroMARK™ Plus vs. HydroMARK™, risks have been determined to be acceptable to risk management policies. |

| ***General Testing Standards Summary*** | |
|---|---|
| **FDA Recognized Testing Standards*:***<br>○ *ISO 13485:2016 Certification – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes process for medical devices*<br>○ *ISO 14971:2019 (Ed.3.0) - Medical Devices - Application of Risk Management to Medical Devices* | ***Conclusion Supporting Substantial Equivalence:*** Design verification process is compliant with Devicor Medical Product's *ISO 13485* Quality Management System. Results of the design verification 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 devices. This evidence in conjunction with the *ISO 14971* compliant Risk Management process supports a determination of substantial equivalence of the Devicor Medical Products, Inc. HydroMARK™ Plus Breast Biopsy Site Marker [subject device] when compared to the Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate devices]. |
| ***Sterilization, Shelf Life and Packaging*** | |
| **HydroMARK™ Plus ETO Sterilization Report** | ***Sterilization:*** **PASSED**<br>Meets standard for ISO 11135:2014 Sterilization of Health Care Products; Ethylene Oxide Requirements for Development, Validation and Routine control of a sterilization process for medical devices. |
| **HydroMARK™ Plus 18M Real-Time Aging Report [device]** | ***Shelf Life [Device]:*** The shelf life for the HydroMARK™ Plus Breast Biopsy Site Marker [subject device] is 1.5 years/18 months. |
| **HydroMARK™ Plus 36M Accelerated Aging [packaging]** | ***Shelf Life [Packaging]:*** HydroMARK™ Plus Breast Biopsy Site Marker [subject device] has been assessed and passed for up to 36 months. |
| ***Conclusion:***<br>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 [subject device] meets all design and functional requirements and is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate device]. | |

Various test reports mentioned above are referenced in further detail in **Section 12: Substantial Equivalence**.

## VIII. CONCLUSIONS

Based on the verification results and a side-by-side comparison of the technological characteristics of design, indication for use / intended use, components, performance and biological data, literature reviews, and materials of construction, it is concluded that the Devicor Medical Products, Inc. HydroMARK™ Plus Biopsy Site Marker [subject device] is substantially equivalent to the Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate devices]. The User Instructions & Operations Guide, Safety Information Booklet, labels, shape of the implantable marker, manufacturing, and packaging have been found to be safe and effective for the intended users, uses, and use environments.

The identical indications for use / intended use, and technological characteristics for the proposed Devicor Medical Products, Inc. HydroMARK™ Plus Biopsy Site Marker [subject device] have been assessed to be substantially equivalent (SE) to the predicate device, and minor differences between the subject device and predicate device design, manufacturing, packaging, and labeling do not raise new or different issues of safety and effectiveness.

Therefore, the Devicor Medical Products, Inc. HydroMARK™ Plus Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate devices].