December 16, 2020

Devicor Medical Products, Inc
Rhonda Kops
Senior Regulatory Manager
300 E-Business Way, Fifth Floor
Cincinnati, Ohio 45241

Re: K203097
Trade/Device Name: HydroMARK Breast Biopsy Site Markers
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: October 12, 2020
Received: October 14, 2020

Dear Rhonda Kops:

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, 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)*
K203097

Device Name
HydroMARK® Breast Biopsy Site Marker

Indications for Use *(Describe)*
The HydroMARK® Breast Biopsy Site Marker is indicated 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.**

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*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 U.S.A.

***Establishment Registration Number***
3008492462

***Official Correspondent for Devicor Medical Products, Inc.***
Rhonda M. Kops, RAC
*Phone:* (513)-864-9272 (office)
*Email:* rhonda.kops@mammotome.com

***Date Prepared***
October 12, 2020

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

| | |
|---|---|
| *Device Trade/Proprietary Name:* | **HydroMARK® Breast Biopsy Site Marker** |
| *Device Common or Usual Name:* | Implantable Clip |
| *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 [510(k) Submission] |
| *Review Panel:* | General & Plastic Surgery |
| *Premarket Review:* | Surgical and Infection Control Devices (OHT4)<br>Infection Control and Plastic Surgery Devices (DHT4B) |

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

| | |
|---|---|
| ***Predicate Device:*** | The Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Sponsor's own predicate device:<br>• **Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device]**<br>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 (K161021) [predicate device] 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 usability, functionality, and performance characteristics as the predicate device. |

| | |
|---|---|
| **Reference Device:** | The Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Sponsor's own reference device:<br>• **Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K121113 and K130537) [reference device]**<br>The Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] is additionally substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K121113 and K130537) [reference device] 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 usability, functionality, and performance characteristics as the reference device. |

## 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 applicator devices designed to fit into the following:

- **8G Flexible Applicator System** fits into:
  - Mammotome *revolve*® 8G Probe (9cm with and without Specimen Management System and 12cm without Specimen Management System)
  - EnCor 7G Directional Vacuum-Assisted Biopsy Devices
- **10G Flexible Applicator System** fits into:
  - Mammotome *revolve®* 10G Probe (9cm with and without Specimen Management System and 12cm without Specimen Management System)
  - EnCor 10G Directional Vacuum-Assisted Biopsy Devices
  - ATEC 9G Biopsy Handpiece Introducers

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. 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. The wire coil is available in (3) three shapes:

| | |
|---|---|
|  | • **Barrel Shape:** Model Numbers [4010-05-08-T1 and 4010-05-10-T1] |
|  | • **Open Coil Shape:** Model Numbers [4010-05-08-T3 and 4010-05-10-T3] |
|  | • **Butterfly Shape:** Model Numbers [4010-05-08-T4 and 4010-05-10-T4] |

The table below provides details of each HydroMARK® Breast Biopsy Site Marker including the model number, material, shape type/shape, and the length/OD of the marker and hydrogel.

***HydroMARK® Breast Biopsy Site Marker Coil Types & Shapes and Marker/Hydrogel Length/OD***

| *Model Number* | *Material* | *Shape Type* | *Shape* | *Marker Length/OD* | *Hydrogel Length/OD* |
|---|---|---|---|---|---|
| 4010-05-08-T1 | Titanium | Barrel |  | L: 0.039 – 0.049”<br>OD: 0.034 – 0.039” | L: 0.140-0.20”<br>OD:0.069-0.080” |
| 4010-05-08-T3 | Titanium | Open Coil |  | L: 0.061 – 0.081”<br>OD: 0.034 – 0.039” | L: 0.140-0.20”<br>OD:0.069-0.080” |
| 4010-05-08-T4 | Titanium | Butterfly |  | L: 0.060– 0.080”<br>OD: 0.022 – 0.027” | L: 0.140-0.20”<br>OD:0.069-0.080” |
| 4010-05-10-T1 | Titanium | Barrel |  | L: 0.039 – 0.049<br>OD: 0.034 – 0.039 | L: 0.140-0.20”<br>OD:0.069-0.073” |
| 4010-05-10-T3 | Titanium | Open Coil |  | L: 0.061 – 0.081<br>OD: 0.034 – 0.039 | L: 0.140-0.20”<br>OD:0.069-0.073” |
| 4010-05-10-T4 | Titanium | Butterfly |  | L: 0.060– 0.080<br>OD: 0.022 – 0.027 | L: 0.140-0.20”<br>OD:0.069-0.073” |

## V. INTENDED USE *[Per 807.92(a)(5)]*

The HydroMARK® Breast Biopsy Site Marker [subject device] is intended to mark tissue during a percutaneous breast biopsy procedure.

*The Intended Use of the HydroMARK® Breast Biopsy Site Marker [subject device] and the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] are identical. Both devices are intended to mark tissue during a percutaneous breast biopsy procedure.*

## VI. INDICATIONS FOR USE *[Per 807.92(a)(5)]*

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.

*The Indications for Use Statement for the Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] is identical to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device].*

## VII. 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 (K161021) [predicate device] 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 differences between the subject device and predicate device do not raise new or different issues of safety and effectiveness. Non-Clinical Performance Testing and Device Compatibility Testing was conducted to demonstrate substantial equivalence (SE).

***Rationale for Substantial Equivalence (SE)***

The Devicor Medical Products, Inc. HydroMARK® Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] in terms of the identical indications for use / intended use and substantially equivalent usability, functionality, and performance characteristics as the predicate device. A detailed description of the similarities shared between the subject device and the predicate device, as well as, a description of the minor differences which do not raise new or different issues of safety and effectiveness, support a determination of substantial equivalency (SE).

***Similarities***

The Devicor Medical Products, Inc. HydroMARK® Biopsy Site Marker [subject device] shares the following same or similar characteristics as the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device]:

- *Intended Use / Indications for Use:* Identical. The HydroMARK® Biopsy Site Marker [subject device] 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.
- *Marker Length:* Same
- *Marker Outer Diameter:* Same
- *Marker Cylinder Composition:* Same
- *Marker Coil Composition:* Same
- *Plunger Rod Material:* Same
- *Insertion Method into Biopsy Device:* Same
- *Marker to Biopsy Prove Alignment Confirmation:* Same
- *Deployment Action:* Same
- *Sterile Device:* Same
- *Sterility Assurance Level:* Same
- *Sterilization Method:* Same
- *Prescription Use:* Same
- *Use Environment:* Same

***Differences***

There are minor differences that exist between the Devicor Medical Products, Inc. HydroMARK® Biopsy Site Marker [subject device] when compared to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] which do not raise new or different questions of safety and effectiveness. Non-Clinical Performance Testing [including: Design Verification by Document Analysis; Compatibility Verification Testing (Deployment and Removal of the Markers in each Probe), Mechanical Verification Testing; Finite Element Analysis (FEA) for the Determination of the Safety Factor of the Daybreak Cannula vs. MammoMARK® Cannula that will reduce tip shear occurrence; Hydrogel Verification Testing; Transit Verification Testing (Climatic Conditioning, Packaging Performance, Gross Leak Detection (Bubble), and Seal Strength (Peel) Testing]; Human Factors/Usability Testing; Biocompatibility Testing; Chemical Characterization Testing; Bioburden Testing; Endotoxin Testing;

Residual Analysis Testing; Sterilization Testing; Sterility Testing; and Shelf-Life Testing, was conducted to demonstrate substantial equivalence (SE). The subject device has the following characteristics which are different from the predicate device:

- *Coil Shapes:* Different. The addition of the T4 butterfly shaped coil to the HydroMARK® Biopsy Site Markers [subject device] does not raise different questions of safety and effectiveness. This T4 butterfly shaped coil is the same as the commercially available T4 butterfly shaped coil used with the reference device cleared under (K130537). The T4 butterfly shaped coil is simply added as a third coil shape option for the subject device. Non-Clinical Performance Testing and Compatibility Testing was conducted to demonstrate substantial equivalence (SE).
- *Overall Length of Device (as shipped):* Different. The minor differences in the overall length of the HydroMARK® Biopsy Site Markers [subject device] (as shipped) does not raise different questions of safety and effectiveness. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).
- *Overall Length of Device (as deployed):* Different. The subject device incorporates deployment detent to prevent plunger from retracting completely to provide further clearance in deployed state for post-procedure confirmation scans and provide user confirmation of successful deployment. The difference in the overall length of the device (as deployed) does not raise new or different questions of safety and effectiveness. Non-Clinical Performance Testing has been conducted to demonstrate substantial equivalence (SE).
- *Plunger Rod Type:* Different. The difference in the plunger rod type (flexible vs. rigid) does not raise new or different questions of safety and effectiveness. The predicate device plunger rod cleared under (K161021) has documented reportable events in the FDA's MAUDE database. Changing to a continuous flexible rod design eliminates these issues. The reference device plunger rod cleared under (K121113 and K130537) is the same flexible rod type as the subject device. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).
- *Plunger Tip Full Stroke Exposure:* Different. The exposure of plunger tip at full stroke has been shortened in the subject device to prevent chance that the tip of the plunger can get caught outside of the cannula and negatively interact with the biopsy prove needle. The difference in the plunger tip full stroke exposure does not raise new or different questions of safety and effectiveness. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).
- *Plunger Rod Material:* Different. The flexible materials used in the subject device are the same as the 4010-01-08 commercialized reference device cleared under (K121113). This difference does not raise new or different questions of safety and effectiveness. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).
- *Marker Aperture Position (Distal Tip to Top of Ramp):* Different. The Marker Aperture Position (Distal Tip to Top of Ramp) in the subject device was moved towards the distal end of the device to improve deployment when the biopsy probe is in smallest aperture setting. This difference in marker aperture position does not raise new or different questions of safety and effectiveness. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).
- *Cannula Type:* Different. The flexible cannula type in the subject device improves usability in Stereotactic procedures where marking through probe is difficult in upright biopsy cases. This difference in the cannula type (flexible versus rigid) does not raise new or different questions of safety and effectiveness. The flexible materials used in the subject device are the same as the 4010-01-08 commercialized reference device cleared under (K121113 and K130537). Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).

- *Cannula Material:* Different. The materials used for the flexible type cannula of the subject device are the same as the 4010-01-08 commercialized reference device cleared under (K121113). This difference does not raise new or different questions of safety and effectiveness. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).
- *Deployment Spring Composition:* Different. The addition of the Stainless-Steel Compression Spring in the subject device ensures that the Plunger Tip fully retracts back into cannula while improving deployment control and feel for user. This difference in the composition of the deployment spring does not raise new or different questions of safety and effectiveness. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).
- *Sterility Guide:* Different. Due to the change from a rigid to flexible cannula in the subject device, this sterility guide is added to the subject device to help users guide the marker into the biopsy device without the need of directly touching the marker tip. This difference does not raise new or different issues of safety or effectiveness. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).
- *Device Bonding:* Different. Due to the change from a rigid to flexible cannula in the subject device, the components are glued. This bonding method and the material is the same as the 4010-01-08 commercialized reference device cleared under (K121113). This difference does not raise new or different questions of safety and effectiveness. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).
- *Sterile Packaging:* The new packaging design will include development of a new carrier card, a protective sheath, sterile pouch, sales carton and shipper.
- *Shelf-Life:* Different. The difference in shelf-life does not raise different questions of safety and effectiveness. Shelf-Life Testing was conducted to demonstrate substantial equivalence (SE).
- *Compatible Biopsy Devices:* Different. The added marker option for 8GA *revolve®* and 7G EnCor (4010-05-08) does not raise new or different questions of safety and effectiveness. Non-Clinical Performance Testing and Device Compatibility Testing was conducted to demonstrate substantial equivalence (SE).
- *Insertion Depth Confirmation:* Different. The Depth Indicators were added to the subject device based on the Voice of Customer (VOC). This difference does not raise new or different questions of safety and effectiveness. Non-Clinical Performance Testing was conducted to demonstrate substantial equivalence (SE).

***Overall Conclusions Regarding Substantial Equivalence (SE)***

The fundamental scientific technology of subject device and the predicate device has not changed. Based on the data generated from the results of the Non-Clinical Performance Testing [including: Design Verification by Document Analysis; Compatibility Verification Testing (Deployment and Removal of the Markers in each Probe), Mechanical Verification Testing; Finite Element Analysis (FEA) for the Determination of the Safety Factor of the Daybreak Cannula vs. MammoMARK® Cannula that will reduce tip shear occurrence; Hydrogel Verification Testing; Transit Verification Testing (Climatic Conditioning, Packaging Performance, Gross Leak Detection (Bubble), and Seal Strength (Peel) Testing]; Human Factors/Usability Testing; Biocompatibility Testing; Chemical Characterization Testing (Exhaustive Extractables and Toxicological Risk Assessment); Bioburden Testing; Endotoxin Testing; Residual Analysis Testing; Sterilization Testing; Sterility Testing; and Shelf-Life Testing conducted on the subject device, it may be concluded that the Devicor Medical Products, Inc. HydroMARK® Biopsy Site Marker [subject device] is as safe and effective, and performs as well as, the legally marketed predicate device, the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device]. The identical indications for use / intended use, and substantially equivalent usability, functionality and

performance characteristics for the proposed the Devicor Medical Products, Inc. HydroMARK® Biopsy Site Marker [subject device] have been assessed to be substantially equivalent (SE) to the predicate device, and any differences do not raise new or different issues of safety and effectiveness when compared to the predicate device.

Therefore, the Devicor Medical Products, Inc. HydroMARK® Biopsy Site Marker [subject device] is substantially equivalent to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] and (K121113 and K130537) [reference device].

## VIII. SUMMARY OF PERFORMANCE DATA AND PERFORMANCE 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 design and functional requirements and is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] and (K121113 and K130537) [reference device]. The following Non-Clinical Performance Data were provided in support of the substantial equivalence (SE) determination.

**Non-Clinical Performance Bench Testing**

- **Non-Clinical Performance Bench Testing** including:
  - **Design Verification by Document Analysis**
  - **Finite Element Analysis (FEA) for the determination of the safety factor of Daybreak Cannula vs. MammoMARK Cannula that will reduce the tip shear occurrence**
  - **Hydrogel Verification Testing**
  - **Compatibility Verification Testing**
    - **Deployment and Removal of the Markers in each Probe**
  - **Mechanical Verification Testing**

**Human Factors/Usability Testing**

- **Human Factors/Usability Testing** including:
  - **Simulated Use Testing**
  - **Formative Studies**

**Biocompatibility Testing**

*Refer to Section 15. Biocompatibility for additional details on the Biocompatibility – GLP Cytotoxicity (MEM Elution) Testing.*

**Biocompatibility Testing** was conducted on the Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] to determine the potential for an unacceptable adverse biological response resulting from contact of the component materials of the device with the body. The results of the Biocompatibility Testing confirmed the biological safety of the subject device and that it is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] and (K121113 and K130537) [reference device]. The following Biocompatibility Data were provided in support of the substantial equivalence (SE) determination.

- **Biocompatibility Testing** including:
  - **GLP Cytotoxicity (MEM Elution) Testing**

**Chemical Characterization Testing (including Exhaustive Extractables and Toxicological Risk Assessment)**
*Refer to Section 15. Biocompatibility for additional details on the Chemical Characterization Testing.*

**Chemical Characterization Testing (including Exhaustive Extractables and Toxicological Risk Assessment)** was conducted on the Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] to assess potential toxicological risks of the device materials. The Chemical Characterization Testing confirmed no unacceptable adverse biological response resulting from contact of the component materials of the device with the body. The results of the Chemical Characterization Testing confirmed the biological safety of the subject device and that it is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] and (K121113 and K130537) [reference device]. The following Biocompatibility Data were provided in support of the substantial equivalence (SE) determination.

- **Exhaustive Extractables Testing (Exhaustive Extractables Report)**
- **Toxicological Risk Assessment**

**Bioburden Testing, Sterilization Testing, Sterility Testing, Endotoxin Testing, Residual Analysis Testing, Transit Verification Testing, 12 Month and 18 Month Shelf-Life Testing**
*Refer to Section 14. Sterilization, Shelf-Life, and Packaging for additional details on these tests.*

**Bioburden Testing, Sterilization Testing, Sterility Testing, Endotoxin Testing, Residual Analysis Testing, Transit Verification Testing, 12 Month and 18 Month Shelf-Life Testing** was conducted on the Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] to confirm that the device meets all design and functional requirements and is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] and (K121113 and K130537) [reference device]. The following Non-Clinical Performance Data were provided in support of the substantial equivalence (SE) determination.

- **Bioburden Testing**
- **Sterilization Testing**
  - **Sterilization Load Configuration / Challenge Device Placements / Biological Indicator Placements**
- **Sterility Testing**
  - **Sterility Testing of the Natural Product**
  - **Sterility Testing of the Biological Indicators**
- **Endotoxin Testing**
- **Residual Analysis Testing**
- **Shelf-Life / Transit Verification Testing**
  - **12 Month Climatic Conditioning, Packaging Performance, Gross Leak Detection (Bubble), and Seal Strength (Peel) Testing**
  - **18 Month Climatic Conditioning, Packaging Performance, Gross Leak Detection (Bubble), and Seal Strength (Peel) Testing**

**High-Level Summary Tables of Non-Clinical Performance Testing**
The table below includes a high-level summary of the Non-Clinical Bench Performance Testing data results submitted, referenced, or relied on in this premarket notification submission [510(k)] for a determination of substantial equivalence (SE).

| *Finite Element Analysis (FEA) Simulation Study for the Determination of the Safety Factor of HydroMARK® Cannula vs. MammoMARK® Cannula that will Reduce the Tip Shear Occurrence* | |
|---|---|
| • **Finite Element Analysis (FEA) Simulation Study for the Determination of the Safety Factor of HydroMARK® Cannula vs. MammoMARK® Cannula that will Reduce the Tip Shear Occurrence** including:<br>- **Safety Factor for HydroMARK® 8G**<br>- **Safety Factor for HydroMARK® 10G**<br><br>***In-House Testing Standards:*** This Finite Element Analysis (FEA) Simulation Study for the Determination of the Safety Factor of the HydroMARK® Cannula vs. the MammoMARK® Cannula that will Reduce the Tip Shear Occurrence was conducted in accordance with In-House Testing Standards as established by Devicor Medical Products, Inc. The FEA Simulation study is based on design requirements of the product and are unique to this product type, there is no recognized testing standard. Devicor has created a procedure for testing that is consistently used for this type of testing. The test is not relevant to the predicate device and was developed for the subject device. | ***Test Results:*** **PASSED**<br>The results of these Finite Element Analysis (FEA) Simulation Study Data were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE):*** The results of the Finite Element Analysis (FEA) Simulation Study for the Determination of the Safety Factor of HydroMARK® Cannula vs. MammoMARK® Cannula that will Reduce the Tip Shear Occurrence 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |
| ***Hydrogel Verification Testing*** | |
| • **Hydrogel Verification Testing** including:<br>- **Hydrogel Hydration Testing**<br>- **Hydrogel Moisture Content Analysis**<br><br>***In-House Testing Standards:*** This Hydrogel Verification Testing was conducted in accordance with In-House Testing Standards as established by Devicor Medical Products, Inc.<br>Hydrogel Verification Testing is based on design requirements of the product and are unique to this product type, there is no recognized testing standard. Devicor has created a procedure for testing that is consistently used for this type of testing and is based on industry best practices for measuring Hydration of Hydrogels via swell ratio measurements. Residual Moisture is completed by a third-party test lab and uses standard Karl Fischer coulometric titration. The testing is based on testing used for the predicate device with additional and more stringent success criteria. | ***Test Results:*** **PASSED**<br>The results of these Hydrogel Verification Testing Data were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE)***: The results of the Hydrogel Verification 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |
| ***Compatibility Verification Testing*** | |
| • **Compatibility Verification Testing** including:<br>- **Deployment and Removal of the Markers in each Probe**<br><br>***In-House Testing Standards:*** This Compatibility Verification Testing was conducted in accordance with In-House Testing Standards as established by Devicor Medical Products, Inc. Marker device compatibility has no relevant ASTM or ISO standard procedure. Devicor has created a procedure for testing that is consistently used for this type of testing. The testing is based on testing used for the predicate device with additional and more stringent success criteria. | ***Test Results:*** **PASSED**<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE):*** The results of the Compatibility Verification 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |
| ***Mechanical Verification Testing*** | |

| | |
|---|---|
| • **Mechanical Verification Testing** including:<br>- **Marker Deployment and Sterile Guide Release Test for 8G & 10G HydroMARK®**<br>- **Pushrod Self Retraction Testing for 8G & 10G HydroMARK®**<br>- **HydroMARK® Bond Strength Testing**<br><br>***In-House Testing Standards:*** This Mechanical Verification Testing was conducted in accordance with In-House Testing Standards as established by Devicor Medical Products, Inc. Mechanical Verification Testing is based on design requirements of the product and are unique to this product type, there is no recognized testing standard. Devicor has created a procedure for testing that is consistently used for this type of testing. The testing is based on testing used for the predicate device with additional and more stringent success criteria. | ***Test Results:*** **PASSED**<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE):*** The results of the Mechanical Verification 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |
| ***Overall Conclusion:*** The data generated from the results of the **Non-Clinical Performance Bench Testing** conducted on the Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] demonstrate that the device is as safe, as effective, and performs as well as, the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] and (K121113 and K130537) [reference device]. Therefore, the data results may be relied on to support a determination of substantial equivalence (SE). | |

**Human Factors/Usability Testing** was conducted on the Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] to confirm the safety and effectiveness of the device for the intended users, uses, and use environments. The results of the Human Factors/Usability Testing confirmed that the subject device has been found to be safe and effective for the intended users, uses and use environments, and that the subject device and that it is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] and (K121113 and K130537) [reference device]. The following Human Factors/Usability Testing data were provided in support of the substantial equivalence (SE) determination.

- **Human Factors/Usability Testing**
- **Formative Studies (FE1) and (FE2)**

The table below includes a high-level summary of the Human Factors/Usability Testing and Formative Studies data results submitted, referenced, or relied on in this premarket notification submission [510(k)] for a determination of substantial equivalence (SE).

| **Human Factors/Usability Testing and Formative Studies** | |
|---|---|
| • **Human Factors/Usability Testing**<br>- Simulated Use Testing<br>- Formative Studies (FE1 and FE2)<br><br>***FDA Recognized Testing Standards:***<br>• IEC 62366-1:2015-*Medical Devices, Part 1: Application of Usability Engineering to Medical Devices*<br>• IEC 60601-1-6:2010 + A1:2013-*Medical Electrical Equipment-Part 1-6: General Requirements for Basic Safety and Essential Performance-Collateral Standard: Usability* | ***Test Results:*** **PASSED**<br>The results of these Non-Clinical Bench Performance Data were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE):*** The results of the Human Factors/Usability Testing and Formative Studies 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |

| | |
|---|---|
| • FDA's Guidance *Applying Human Factors and Usability Engineering to Optimize Medical Device Design* (2016)<br>• IEC 62366-2:2016-*Medical Devices, Part 2: Guidance on the Application of Usability Engineering to Medical Devices* | |

**Biocompatibility Testing** was conducted on the Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] to determine the potential for an unacceptable adverse biological response resulting from contact of the component materials of the device with the body. The results of the Biocompatibility Testing confirmed the biological safety of the subject device and that it is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] and (K121113 and K130537) [reference device]. The following Biocompatibility Data were provided in support of the substantial equivalence (SE) determination.

- **GLP Cytotoxicity (MEM Elution) Testing**

The table below includes the list of the Biocompatibility Testing results submitted, referenced, or relied on in this premarket notification submission [510(k)] for a determination of substantial equivalence (SE).

| ***Summary of Biocompatibility Testing*** | |
|---|---|
| Biocompatibility 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 [510(k)] for a determination of substantial equivalence (SE). | |
| **Biocompatibility Testing (Cytotoxicity MEM Elution)** | |
| • **<u>Biocompatibility Testing</u>** including:<br>- **Cytotoxicity (MEM Elution) Testing**<br><br>***<u>FDA Recognized Testing Standards:</u>***<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 10993-10:2010-*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* | ***<u>Test Results:</u>* PASSED**<br>The results of these Biocompatibility Data were provided in support of the substantial equivalence (SE) determination.<br><br>***<u>Conclusion Supporting Substantial Equivalence (SE):</u>***<br>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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |

**Chemical Characterization Testing (including Exhaustive Extraction and Toxicological Risk Assessment)** was conducted on the Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] to assess potential toxicological risks of the device materials. The Chemical Characterization Testing confirmed no unacceptable adverse biological response resulting from contact of the component materials of the device with the body. The results of the Chemical Characterization Testing

confirmed the biological safety of the subject device and that it is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] and (K121113 and K130537) [reference device]. The following Biocompatibility Data were provided in support of the substantial equivalence (SE) determination.

| ***Summary of Chemical Characterization Testing*** | |
|---|---|
| Chemical Characterization Testing (including Exhaustive Extractables and Toxicological Risk Assessment) 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 [510(k)] for a determination of substantial equivalence (SE). | |
| **Exhaustive Extractables Testing** | |
| • **Exhaustive Extractables Testing**<br><br>***FDA Recognized Testing Standards:***<br>• *ISO 10993-12:2012-Biological evaluation of medical devices-Part 12: Sample preparation and reference materials.*<br>• *ISO 10993-18:2020-Biological evaluation of medical devices-Part 18: Chemical characterization of medical device materials within a risk management process* | ***Test Results:*** **PASSED**<br>The results of these Chemical Characterization Data were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE):***<br>The results of the Chemical Characterization 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |
| **Toxicological Risk Assessment** | |
| • **Toxicological Risk Assessment**<br><br>***FDA Recognized Testing Standards:***<br>• *ISO 10993-1:2018-Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process*<br>• *ISO 10993-18:2020-Biological evaluation of medical devices-Part 18: Chemical characterization of medical device materials within a risk management process*<br>• ISO 10993-17:2002-Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances | ***Test Results:*** **PASSED**<br>The results of these Chemical Characterization Data were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE):***<br>The results of the Chemical Characterization 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |

**Bioburden Testing, Sterilization Testing, Sterility Testing, Endotoxin Testing and Residual Analysis Testing** was conducted on the Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] to confirm the sterility and shelf-life of the device. The results of the Sterilization Testing, Bioburden Testing, and Endotoxin Testing and confirmed the sterility and safety of the subject device and that it is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] and (K121113 and K130537) [reference device]. The following Sterilization Testing, Bioburden Testing, and Endotoxin Testing Data were provided in support of the substantial equivalence (SE) determination.

- **Bioburden Testing**
- **Sterilization Testing**
  - **Sterilization Load Configuration / Challenge Device Placements / Biological Indicator Placements**
- **Sterility Testing**
  - **Sterility Testing of the Natural Product**
  - **Sterility Testing of the Biological Indicators**
- **Endotoxin Testing**
- **Residual Analysis Testing**

| ***Summary of the Bioburden Testing, Sterilization Testing, Sterility Testing, Endotoxin Testing and Residual Analysis Testing*** | |
|---|---|
| Bioburden Testing, Sterilization Testing, Sterility Testing, Endotoxin Testing and Residual Analysis 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 [510(k)] for a determination of substantial equivalence (SE). | |
| **Bioburden Testing** | |
| • **Bioburden Testing**<br><br>***FDA Recognized Testing Standards:***<br>• ANSI/AAMI/ISO 11737-1:2018 – *Sterilization of Health Care Products – Microbiological Methods-Part 1: Determination of a Population of Microorganisms on Products.* | ***Test Results:*** **PASSED**<br>The results of these Bioburden Testing Data were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE):***<br>The results of the Bioburden 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |
| **Sterilization Testing** | |
| • **Sterilization Testing**<br><br>***FDA Recognized Testing Standards:***<br>• ANSI/AAMI/ISO 11737-1:2018 – *Sterilization of Health Care Products – Microbiological Methods-Part 1: Determination of a Population of Microorganisms on Products.* | ***Test Results:*** **PASSED**<br>The results of these Sterilization Testing Data were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE):***<br>The results of the Sterilization 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |
| **Sterility Testing of the Natural Product** | |
| • **Sterility Testing of the Natural Product**<br><br>***FDA Recognized Testing Standards:*** | ***Test Results:*** **PASSED**<br>The results of these Sterility Testing of the Natural Product Data were provided in support of the substantial equivalence (SE) determination. |

| | |
|---|---|
| • ANSI/AAMI/ISO 11737-1:2018 – *Sterilization of Health Care Products – Microbiological Methods-Part 1: Determination of a Population of Microorganisms on Products.* | ***Conclusion Supporting Substantial Equivalence (SE):***<br>The results of the Sterility Testing of the Natural Product 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |
| **Sterility Testing of the Biological Indicators** | |
| • **Sterility Testing of the Biological Indicators**<br><br>***FDA Recognized Testing Standards:***<br>• ANSI/AAMI/ISO 11737-1:2018 – *Sterilization of Health Care Products – Microbiological Methods-Part 1: Determination of a Population of Microorganisms on Products.* | ***Test Results:*** **PASSED**<br>The results of these Sterility Testing of the Biological Indicators Data were provided in support of the substantial equivalence (SE) determination.<br>***Conclusion Supporting Substantial Equivalence (SE):***<br>The results of the Sterility Testing of the Biological Indicators 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |
| **Endotoxin Testing** | |
| • **Endotoxin Testing**<br><br>***FDA Recognized Testing Standards:***<br>• USP <85> *Bacterial Endotoxins Testing*<br>• ANSI/AAMI ST72: *Bacterial Endotoxins – Test Methods* | ***Test Results:*** **PASSED**<br>The results of these Endotoxin Testing Data were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE):***<br>The results of the Endotoxin 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |
| **Residual Analysis Testing** | |
| • **Residual Analysis Testing**<br><br>***FDA Recognized Testing Standards:***<br>• *USP <85> Bacterial Endotoxins Testing*<br>• *ANSI/AAMI ST72: Bacterial Endotoxins – Test Methods* | ***Test Results:*** **PASSED**<br>The results of these Residual Analysis Testing Data were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE):***<br>The results of the Residual Analysis 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |

**Shelf-Life Testing / Transit Verification Testing** was conducted on the Devicor Medical Products, Inc. HydroMARK® Breast Biopsy Site Marker [subject device] to confirm the twelve (12) Month and eighteen (18) Month Shelf-Life of the device. The results of the 12 Month Aging Testing / 18 Month Aging Testing confirmed the shelf-life of the subject device and that it is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] and (K121113 and K130537) [reference device]. The following Shelf-Life Testing Data were provided in support of the substantial equivalence (SE) determination.

- **Shelf-Life / Transit Verification Testing (12 Month Aging) – Climatic Conditioning, Packaging Performance, Gross Leak Detection (Bubble), and Seal Strength (Peel) Testing**
- **Shelf-Life / Transit Verification Testing (12 Month Aging) – Climatic Conditioning, Packaging Performance, Gross Leak Detection (Bubble), and Seal Strength (Peel) Testing**

| **Shelf-Life Testing / Transit Testing (12 Month Aging) - Climatic Conditioning, Packaging Performance, Gross Leak Detection (Bubble), and Seal Strength (Peel) Testing** | |
|---|---|
| • **Shelf-Life / Transit Verification Testing (12 Month Aging) – Climatic Conditioning, Packaging Performance, Gross Leak Detection (Bubble), and Seal Strength (Peel) Testing**<br><br>***FDA Recognized Testing Standards:***<br>• ASTM F1980-16: *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*<br>• ASTM F2095-11: *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)*<br>• ASTM F38/F88M-15: *Standard Test Method for Seal Strength of Flexible Barrier Materials* | ***Test Results:*** **PASSED**<br>The results of these Shelf-Life Testing (12 Month Aging) were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE):***<br>The results of the Shelf-Life Testing (12 Month Aging) 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |
| **Shelf-Life Testing / Transit Testing (18 Month Aging) - Climatic Conditioning, Packaging Performance, Gross Leak Detection (Bubble), and Seal Strength (Peel) Testing** | |
| • **Shelf-Life / Transit Verification Testing (18 Month Aging) – Climatic Conditioning, Packaging Performance, Gross Leak Detection (Bubble), and Seal Strength (Peel) Testing**<br><br>***FDA Recognized Testing Standards:***<br>• ASTM F1980-16: *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices*<br>• ASTM F2095-11: *Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)*<br>ASTM F38/F88M-15: *Standard Test* | ***Test Results*: PASSED**<br>The results of these Shelf-Life Testing (18 Month Aging) were provided in support of the substantial equivalence (SE) determination.<br><br>***Conclusion Supporting Substantial Equivalence (SE):***<br>The results of the Shelf-Life Testing (18 Month Aging) 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 (K161021) [predicate device] and (K121113 and K130537) [reference device]. |

| | |
|---|---|
| *Method for Seal Strength of Flexible Barrier Materials* | |

**IX. OVERALL CONCLUSIONS**

The data generated from the results of the following testing conducted on the HydroMARK® Breast Biopsy Site Marker [subject device] demonstrate that the device is as safe, as effective, and performs as well as, the Devicor Medical Products Inc. HydroMARK® Breast Biopsy Site Marker (K161021) [predicate device] and (K121113 and K130537) [reference device]. Therefore, these data results may be relied on to support a determination of substantial equivalence (SE).