January 12, 2024

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

Re: K232615
Trade/Device Name: LumiMARK™ Biopsy Site Marker (LM0215T (Tulip Shape)); LumiMARK™ Biopsy Site Marker (LM0215L (Lotus Shape)); LumiMARK™ Biopsy Site Marker (LM0215R (Rose shape))
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: August 28, 2023
Received: December 15, 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 (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of

Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic.

See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Tek N. Lamichhane -S

Digitally signed by Tek N. Lamichhane -S
Date: 2024.01.12 15:47:59 -05'00'

Tek Lamichhane, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic and Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

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)*
K232615

Device Name
LumiMARK™ Biopsy Site Marker (LM0215T (Tulip Shape));
LumiMARK™ Biopsy Site Marker (LM0215L (Lotus Shape));
LumiMARK™ Biopsy Site Marker (LM0215R (Rose shape))

Indications for Use *(Describe)*
The LumiMARK™ Biopsy Site Marker is indicated to mark tissue associated with a percutaneous breast biopsy procedure, including axillary lymph nodes, and be permanently visible under ultrasound, 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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"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-K232615

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.
Katy Austin, Senior Regulatory Affairs Specialist
Email: katy.austin@mammotome.com

Date Prepared
January 12, 2024

DEVICE ***[Per 807.92(a)(2)]***

Device Trade/Proprietary Name:	LumiMARK™ Biopsy Site Marker (LM0215T (Tulip Shape)) LumiMARK™ Biopsy Site Marker (LM0215L (Lotus Shape)) LumiMARK™ Biopsy Site Marker (LM0215R (Rose Shape))
Regulation Description	Implantable Marker
Device Common or Usual Name:	Marker, Radiographic, Implantable
Device Regulatory Classification:	Class II
Device Classification Regulation:	21 CFR §878.4300
Product Code:	(NEU) – Marker, Radiographic, Implantable
Submission Type:	Traditional 510(k) Premarket Notification
Classification Panel:	General & Plastic Surgery
Premarket Review:	Surgical and Infection Control Devices (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)

PREDICATE DEVICE [Per 807.92(a)(3)]

Predicate Device	The Devicor Medical Products, Inc. LumiMARK™ Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Sponsor's own predicate devices: • **Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (**K212158**) [predicate device]** The Devicor Medical Products, Inc. LumiMARK™ Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate device] in terms of similar Indications for Use / Intended Use to mark tissue during or associated with a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and MRI. The Devicor Medical Product, Inc. LumiMARK™ Biopsy Site Marker

	(subject device) includes axillary lymph nodes in the Indications for Use/Intended Use statement as a direct puncture device, also demonstrated in HydroMARK™ as cleared in K212158. • Substantial equivalence (SE) of the subject device is based on substantially equivalent design, functionality, and performance characteristics as the predicate device.

DEVICE DESCRIPTION [Per 807.92(a)(4)]

The LumiMARK™ Biopsy Site Marker implant component [subject device] is composed of a nitinol (nickel/titanium alloy) material versus HydroMARK™ Breast Biopsy Site Marker [predicate device] which is composed of titanium or stainless steel encapsulated in resorbable hydrogel. The marker is not intended to be removed unless the marked tissue is determined to require surgical removal. The marker is supplied pre-loaded in a sterile, disposable applicator that allows the marker to be inserted with direct puncture under ultrasound. The applicator system is of similar design and materials as the currently marketed Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate device].

LumiMARK™ Biopsy Site Markers will be available in three different shapes. These permanently visible, implantable markers will allow the physician to identify different biopsied sites under ultrasound, x-ray, and MRI. A similar marker device commercialized by Devicor Medical Products, Inc. is already available (under K212158), and this HydroMARK™ Breast Biopsy Marker [predicate].

The deployment system used for the LumiMARK™ Biopsy Site Marker device [subject] will be similar to the HydroMARK™ Breast Biopsy Site Marker [predicate] delivery system with minor design changes to the plunger assembly and cannula. The nitinol markers will be intended for direct puncture or insertion through another introducer needle that is already in the breast or axillary lymph node.

Product Code	Description	Shape
LM0215T	LumiMARK Biopsy Site Marker “Tulip shape”	
LM0215L	LumiMARK Biopsy Site Marker “Lotus shape”	
LM0215R	LumiMARK Biopsy Site Marker “Rose shape”	

This Traditional 510(k) is being submitted to introduce LumiMARK™ Biopsy Siter Markers to the marketplace as part of the Mammotome brand, and the fundamental scientific technology when compared to the HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate device] has not changed. Both subject and predicate will have 3 year/36 month shelf life.

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

INDICATIONS FOR USE

[Per 807.92(a)(5)

The LumiMARK™ Biopsy Site Marker is indicated to mark tissue associated with a percutaneous breast biopsy procedure, including axillary lymph nodes, and be permanently visible under ultrasound, x-ray and MRI.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

[Per 807.92(a)(6)]

The Devicor Medical Products, Inc. LumiMARK™ Biopsy Site Marker [subject device] is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate device] based on the similar functional and performance characteristics of the subject device when compared to the predicate device. The minor differences between the subject device and predicate device do not raise concerns of safety and effectiveness.

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

LumiMARK Comparison to Predicate HydroMARK Breast Biopsy Site Marker (K212158)			
Regulatory Information	**Project Nike LumiMARK™ Biopsy Site Marker [subject]**	**HydroMARK™ Breast Biopsy Site Marker K212158**	**Comparison**
Manufacturer	Devicor Medical Products De Mexico S De RL De CV	Devicor Medical Products De Mexico S De RL De CV	----
Device Trade or Proprietary Name	LumiMARK™ Biopsy Site Marker	HydroMARK™ Breast Biopsy Site Marker	----
510(k) Number	K232615	K212158	**N/A**
Device Class	Class II	Class II	**Substantially Equivalent**
Device Classification Name	Marker, Radiographic, Implantable	Marker, Radiographic, Implantable	**Substantially Equivalent**
Device Common Name	Implantable Marker	Implantable Marker	**Substantially Equivalent**
Product Code	(NEU) – Marker, Radiographic, Implantable	(NEU) – Marker, Radiographic, Implantable	**Substantially Equivalent**
Regulation Number	21 CFR §878.4300	21 CFR §878.4300	**Substantially Equivalent**

Design Features and Capabilities of the Device			
Indications for Use	To mark tissue associated with a percutaneous breast biopsy procedure, including axillary lymph nodes, and be permanently visible under ultrasound, 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.	**Substantially Equivalent**
Prescription or Over-the-Counter (OTC) Use	Prescription	Prescription	**Substantially Equivalent**
Use Environment			
Sterile	Yes	Yes	**Same**
Single-Use	Yes	Yes	**Same**
Design Features			
Marker Material	Nitinol (50% Nickel, 50% Titanium)	Stainless Steel or Titanium marker, surrounded by hydrogel	**Substantially Equivalent**
Marker Shape	Tulip (LM0215T) Lotus (LM0215L) Rose (LM0215R)	Barrel (T1, S1) Butterfly (T4) Open Coil (T3, S3)	**Substantially Equivalent**
Cannula Type	Rigid	Rigid	**Substantially Equivalent**
Cannula Material	Stainless Steel	Stainless Steel	**Substantially Equivalent**
Plunger Rod Material	Stainless Steel	Stainless Steel	**Substantially Equivalent**
Plastic Handle	Plastic Polymer	Plastic Polymer	**Substantially Equivalent**
Plunger Lock	P Plastic Polymer	Plastic Polymer	**Substantially Equivalent**
Plastic Plunger Button	Plastic Polymer	Plastic Polymer	**Substantially Equivalent**
Shelf Life	3 years/36 months	3 years/36 months	**Substantially Equivalent**
Biocompatibility results	- Chemical Characterization - Cytotoxicity - Sensitization - Irritation - Acute Systemic Toxicity - Pyrogenicity - Subacute/ Chronic/ Subchronic Toxicity - Implantation - Genotoxicity - Carcinogenicity	- Chemical Characterization - Cytotoxicity - Sensitization - Irritation - Acute Systemic Toxicity - Pyrogenicity - Subacute/ Chronic/ Subchronic Toxicity - Implantation - Genotoxicity - Carcinogenicity	**Substantially Equivalent**
Performance evaluation testing	- Marker Size - Deployment Force - Visibility	- Marker Size - Deployment Force - Visibility	**Substantially Equivalent**

MR Testing Results			
MR Status for Marker	MR Conditional	MR Conditional	**Substantially Equivalent**
MR Status for Applicator	MR Unsafe	MR Unsafe	**Substantially Equivalent**

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

Summary of Performance Testing	
Performance Testing was conducted on the Devicor Medical Products, Inc. LumiMARK™ Biopsy Site Marker [subject device] to confirm that the device meets all system requirements and is substantially equivalent (SE) to the Devicor Medical Products Inc. HydroMARK Breast Biopsy Site Marker (K212158) [predicate device]. The following Verification Data was provided in support of the substantial equivalence (SE) determination.	
Performance Testing	
Performance Testing LumiMARK™	***Test Results:*** **PASSED** The results of all performance testing met acceptance criteria and are provided in support of the substantial equivalence determination.
LumiMARK™ Risk Management	***Results:*** All risks have been reduced as far as possible through allowed controls: Inherent safety by design, information for safety, and/or preventative measures. There are no unacceptable residual risks at this time. The overall residual risk arising from individual and cumulative risk is acceptable. Benefits outlined are greater than the risks. The product is considered State-of-the-Art.
• ***FDA Recognized Testing Standards:*** ○ *ISO 13485:2016 Certification – Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes process for medical devices* ○ *ISO 14971:2019 (Ed.3.0) – Medical Devices - Application of Risk Management to Medical Devices*	***Conclusion Supporting Substantial Equivalence:*** The results of the design verification carried out within Devicor Medical Product's *ISO 13485:2016* compliant Quality Management System conducted on the LumiMARK™ Biopsy Site Marker [subject device] demonstrates that the subject device is as safe and as effective as the legally marketed predicate device. This evidence in conjunction with the *ISO 14971:2019* compliant Risk Management process supports a determination of substantial equivalence of the Devicor Medical Products, Inc. LumiMARK™ Biopsy Site Marker [subject device] when compared to the Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate devices].

<table>
<tr><th colspan="2">Biocompatibility Testing</th></tr>
<tr><td><u>Biocompatibility Testing</u> including:
Chemical Characterization
Cytotoxicity
Sensitization
Irritation
Acute Systemic Toxicity
Material-Mediated Pyrogenicity
Subacute/Subchronic/ Chronic Toxicity
Implantation Effects
Genotoxicity
Carcinogenicity</td><td><u>Test Results:</u> PASSED
The results of these Non-Clinical Bench Performance Data are provided in support of the substantial equivalence determination.</td></tr>
<tr><td><u>FDA Recognized Testing Standards:</u>
ISO 10993-1:2018-Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process
ISO 10993-3:2014 Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009-Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity
ISO 10993-6:2016-Biological Evaluation of Medical Devices – Part 6: Tests for local effects after implantation
ISO 10993-10:2010-Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization
ISO 10993-11:2017-Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
ISO 10993-17:2002 Biological Evaluation of Medical Devices – Part 17: Establishment of allowable limits for leachable substances
ISO 10993-18:2020 Biological Evaluation of Medical Devices – Part 18: Chemical characterization of medical device materials within a risk management process
ISO 10993-23:2021 Biological Evaluation of Medical Devices – Part 23: Tests for Irritation</td><td><u>Conclusion Supporting Substantial Equivalence:</u> 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 (K212158) [predicate device].</td></tr>
<tr><td colspan="2">Conclusion: The results of the Verification Testing support the safety of the device and demonstrate that the Devicor Medical Products, Inc. LumiMARK™ 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].</td></tr>
</table>

SUBSTANTIAL EQUIVALENCE SUMMARY / CONCLUSIONS

Based on the verification results and a side-by-side comparison of the technological characteristics of design, indication for use / intended use, components, and materials of construction, it is concluded that the Devicor Medical Products, Inc. LumiMARK™ Biopsy Site Marker (K232615) [subject device] is substantially equivalent to the Devicor Medical Products Inc. HydroMARK™ Breast Biopsy Site Marker (K212158) [predicate device].