DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 15, 2017

Devicor Medical Products, Inc.
Ms. Shawna Rose
Sr. Director, QRA
300 E-Business Way, Fifth Floor
Cincinnati, Ohio 45241

Re: K170803
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: March 13, 2017
Received: March 17, 2017

Dear Ms. Rose:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170803

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

The following information is provided as required by 21 CFR § 807.92 for the HydroMARK® Breast Biopsy Site Marker 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990 the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

Company:

Devicor® Medical Products, Inc.
300 E-Business Way, Fifth Floor
Cincinnati, OH 45241
Establishment Registration Number: 3008492462

Contact:

Shawna Rose
Sr. Director, Quality and Regulatory Affairs
Devicor Medical Products, Inc.
300 E-Business Way, Fifth Floor
Cincinnati, OH 45241
Ph: 513-864-9178
Fax: 513-864-9011
E-mail: shawna.rose@leicabiosystems.com

Date of Submission: March 13, 2017

Proprietary Name: HydroMARK® Breast Biopsy Site Marker

Common Name: Breast Biopsy Site Marker

Regulation: 21 CFR 878.4300

Regulatory Class: II

Product Codes: NEU

Classification Name: General and Plastic Surgery Panel

Predicate Devices: HydroMARK® Breast Biopsy Site Markers (K161021) (Primary Predicate)
HydroMARK® Breast Biopsy Site Markers (K121113) (Reference Predicate)
HydroMARK® Breast Biopsy Site Markers (K130537) (Reference Predicate)

Device Description:
The HydroMARK® Breast Biopsy Site Marker contains a resorbable hydrogel component and a metallic component for permanent marking. The hydrogel has features that are unique and highly desirable for breast tissue marking.

The HydroMARK® Breast Biopsy Site Marker is provided pre-loaded in a sterile, disposable applicator that is compatible with specified commercially available biopsy devices. The marker is deployed by the delivery system and is left in the tract created during the biopsy procedure.

This Traditional 510(k) addresses the qualification and validation of a new source of raw material polymer of the same original formulation, produced in a new facility and in smaller batch sizes, to be used by the manufacturer of the hydrogel component of the HydroMARK® Breast Biopsy Site Marker. The hydrogel component is manufactured by Coldstream Laboratories, Inc. The new source of polymer for the hydrogel is Corden Pharma, replacing Genzyme polymer.

Intended Use:

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 are identical to those of the predicate device, the HydroMARK® Breast Biopsy Site Marker, 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.”

Technological Characteristics:

The hydrogel component expands on fluid contact to fill the track of the biopsy needle anchoring the HydroMARK® Breast Biopsy Site Marker at the exact location of biopsy. Because the hydrogel is hydrophilic, it is clearly distinct from normal breast structure under ultrasound imaging. The hydrogel material degrades via hydrolysis over time leaving the internal stainless steel or titanium coil which provides permanent visibility under x-ray and MRI. The hydrogel material uses polymer raw material from a new suppler which has been shown to be chemically equivalent to the original raw material using molecular weight distribution, nuclear magnetic resonance spectra, and degradation profiles from gel permeation chromatography and high performance liquid chromatography.

Non-clinical testing of the modified finished HydroMARK® Breast Biopsy Site Markers is identical to the tests used in the original 510(k) and includes the following:

- Visual inspection
- Critical dimensions
- % Moisture
- Functional Deployment
- Hydration Rate
- Visibility under ultrasound, x-ray and MRI
- Sterility, bioburden, pyrogens, and EO residuals

The finished devices performed as intended according to the specifications established for the original device. The change to the polymer vendor had no impact to the finished products as demonstrated by repeating the original test protocols and meeting the pre-established acceptance criteria. The modified devices are substantially equivalent to the predicate devices.

The modified HydroMARK® Breast Biopsy Site Markers are compared to those cleared in the prior 510(k) submissions in the table below.

PREDICATE DEVICE COMPARISON TABLE

Feature / Technological Characteristics	**Modified HydroMARK® Breast Biopsy Site Marker**	**HydroMARK® Breast Biopsy Site Markers (predicates) K161021 (Primary) K121113 (Reference) K130537 (Reference)**
Device	Breast biopsy marker	Breast biopsy marker
Resorbable component	Polymerized and Desiccated Hydrogel with Corden Pharma polymer	Polymerized and Desiccated Hydrogel with Genzyme polymer
Permanent component	Titanium (grade 2) Stainless steel	Titanium (grade 2) Stainless steel
Marker outer diameter	0.070 inches	0.070 inches
Marker length	0.20inches	0.20inches
Coil (permanent component) length	0.035-0.0625inches	0.035-0.0625inches
Coil (permanent component) width	0.039 inches	0.039 inches
Detection	Ultrasound, x-ray and MRI	Ultrasound, x-ray and MRI
Sterilization	ETO	ETO
Delivery system (non-patient contacting)	Flexible, Rigid , and Rigid Sharp styles	Flexible, Rigid , and Rigid Sharp styles

Finished Product Performance Testing

The polymer used in the hydrogel was historically manufactured by Genzyme in their Lexington, Massachusetts facility. Genzyme transferred the process to their Swiss facility. This facility was later purchased by Corden Pharma. This polymer will now be made in the Corden Pharma Liestal, Switzerland facility in smaller batches than Genzyme originally used, but to the same specifications. The equipment, batch size and processes were qualified by testing 3 consecutive test batches from Liestal, Switzerland to the original specifications. The three manufacturing batches were combined and used to prepare HydroMARK® Breast Biopsy Site Markers which met all original finished product specifications to demonstrate that the changes in polymer manufacturing have had no effect on the finished product.

The following tests were performed to demonstrate substantial equivalence:

Reference No.	Title
ISO 11135	Sterilization of health care products-Ethylene Oxide, Part I, Requirements for development, validation, and routine control of sterilization process for medical devices.
ISO 10993-1	Biological evaluation of medical devices, Part 1: Evaluating and testing within a risk management process.
ISO 10993-5	Biological evaluation of medical devices, Part 5: Tests for in vitro Cytoxicity
ISO 10993-11	Biological evaluation of medical devices, Part 11: Tests for systemic toxicity
ISO 10993-18	Biological evaluation of medical devices, Part 18: Chemical characterization of materials
ASTM F2182-11a	Standard test method for measurement of radio frequency induced heating on or near passive implants during magnetic resonance imaging.
ASTM F2119-07	Standard test method for evaluation of magnetic resonance image artifacts from passive implants
ASTM F2213-06	Standard test method for measurement of magnetically induced torque on medical devices in the magnetic resonance environment
ASTM F2503-13	Marking medical devices and other items for safety in the magnetic resonance environment
ASTM F2052-15	Standard test method for measurement for magnetically induced displacement force on medical devices in the magnetic resonance environment.

- Visual Inspection – free of visual defects
- Critical Dimensions – outer diameter and length
- % Moisture – pre- and post-sterilization
- Functional Deployment
- Hydration Rate
- Visibility under ultrasound, x-Ray and MRI imaging modalities
- Sterilization method
- Bioburden
- Pyrogens
- EO residuals

Polymer Equivalence Testing

Gel permeation chromatography, NMR analyses and degradation profiles were used to establish the equivalency of the raw material polymers

Three samples each of the predicate polymer and the new polymer, both of identical formulations, were tested by gel permeation chromatography with differential refractive index detection. Results show the number (Mn) and weight averaged (Mw) molecular weights obtained from both sources are comparable. The polymer molecular weight distributions for both manufacturers are equivalent. There is no evidence of changed polymer composition that would have ramifications in further processing of the polymer. Therefore no unanticipated reactions are expected to be encountered during subsequent hydrogel production.

The possibility of new chemical entities being created at the new polymer manufacturing facility was studied using nuclear magnetic resonance (NMR). Ratios of chemicals from the first reaction step demonstrate equivalency. NMR was also used to determine molar ratios of the secondary reaction step and also showed equivalency.

Polymer from both synthesis sites was compared in every way. The results of the processes for the predicate and the new material are identical. No different or new chemical entities are identified.

Substantial Equivalence Discussion

The raw material polymer used to make the hydrogel component of the modified HydroMARK® Breast Biopsy Site Markers was demonstrated to be equivalent to the original polymer. Material characterization testing with gel permeation chromatography established equivalent molecular weight distribution and polydispersity between the two sources of the material. Nuclear magnetic resonance established the chemical ratios from each of the two reaction steps were equivalent. No new or different chemical entities were identified. Finally, hydrolysis of both

predicate and new polymers contained the same components, in the same proportions. Both raw material polymers are chemically equivalent.

Conclusion

HydroMARK® Breast Biopsy Site Markers manufactured with hydrogel made from Corden Pharma raw material polymer met all original finished product specifications including visual inspection, dimensions, % moisture, functional deployment, hydration rate, visibility by ultrasound, x-ray and MRI, sterility, bioburden, pyrogens and ethylene oxide residuals. The finished product HydroMARK® Breast Biopsy Site Markers made with Corden Pharma raw material polymer are substantially equivalent to the predicate devices.