



September 16, 2024

View Point Medical
% Randy Prebula
Partner
Hogan Lovells US LLP
555 13th St. NW
Washington, District of Columbia 20004

Re: K241762
Trade/Device Name: OneMark
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: June 18, 2024
Received: June 20, 2024

Dear Randy Prebula:

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: 2024.09.16
20:36:03 -04'00'

Tek N. Lamichhane, Ph.D.

Assistant Director

DHT4B: Division of 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

Indications for Use

Submission Number (if known)

K241762

Device Name

OneMark

Indications for Use (Describe)

The OneMark Breast Localization Marker is intended to be placed percutaneously in soft tissue (>30 days) to mark a biopsy site or soft tissue intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or detection imaging (OneMark Detection Imaging System), the OneMark Breast Localization Marker is located and may be surgically removed with the target tissue. The OneMark Detection Imaging System is intended only for the detection of the OneMark Breast Localization Marker.

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.

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510(k) Summary

DATE PREPARED

August 27, 2024

MANUFACTURER AND 510(k) OWNER

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REPRESENTATIVE/CONSULTANT

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DEVICE INFORMATION

Proprietary Name/Trade Name: OneMark
 Common Name: Biopsy site marker
 Regulation Number: 21 CFR 878.4300
 Class: II
 Product Code: NEU
 Premarket Review: OHT4/ Plastic Surgery and Reconstructive Devices (DHT4B)
 Review Panel: General & Plastic Surgery

PREDICATE DEVICE IDENTIFICATION

OneMark is substantially equivalent to the following predicates:

| <i>510(k) Number</i> | <i>Predicate Device Name / Manufacturer</i> | <i>Predicate</i> |
|----------------------|--|-------------------|
| K181007 | Cianna Medical Scout Reflector and Scout System / Cianna Medical, Inc. | Primary predicate |
| K190689 | SignalMark Breast Marker / View Point Medical, Inc. | Reference device |
| K212158 | HydroMARK Breast Biopsy Site Marker / Devicor Medical Products, Inc. | Reference device |

The predicate devices have not been subject to a design related recall.

DEVICE DESCRIPTION

OneMark is an integrated localization system consisting of the OneMark Detection Imaging System and the OneMark Breast Localization Marker preloaded in an injector device. The OneMark Detection Imaging System is an ultrasound-based intraoperative inspection tool used by clinicians to localize the OneMark Breast Localization Marker, a hydrogel pellet implanted in tissue to mark the site of a lesion. The primary goal of the system is to aid a surgeon in resection of a marked cancer lesion. The system may be used to inspect the marked tissue in all typical workflow situations from initial implant post-biopsy through resection and ex-vivo specimen review.

INDICATIONS FOR USE

The OneMark Breast Localization Marker is intended to be placed percutaneously in soft tissue (>30 days) to mark a biopsy site or soft tissue intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or detection imaging (OneMark Detection Imaging System), the OneMark Breast Localization Marker is located and may be surgically removed with the target tissue. The OneMark Detection Imaging System is intended only for the detection of the OneMark Breast Localization Marker.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

View Point Medical believes that OneMark is substantially equivalent to the predicate devices based on the information summarized here:

The subject device has the same intended use as the primary predicate. Both the subject device and the primary predicate are intended as an aid in resecting a marked cancer lesion by providing a marker to be implanted in the suspected tissue and a detection system for the implanted marker during resection surgery.

The subject device has a similar design as the primary predicate. Both the subject device and the primary predicate feature similar components to achieve the intended effect: a marker, a marker delivery system, a handpiece/probe and a display console. The subject device has similar materials for the delivery system, the handpiece/probe and the display console components as the primary predicate device (e.g., molded plastics, stainless steel).

The main technological differences of OneMark, as compared to the primary predicate, are:

- Type of energy/Principle of operation. OneMark Breast Marker is a passive implant that includes silica microspheres as compared to a micro-impulse radar (SAVI Scout System). The silica microspheres do not emit any form of energy. Instead, they reflect a phase shift when exposed to ultrasound energy which can be processed into a vibrant color image to visualize the marker's location. The amount of ultrasound energy necessary for the OneMark Detection System to locate the OneMark Breast Marker is similar to the amount of ultrasound energy necessary to locate the reference predicate marker

(SignalMark Breast Marker). This difference with the primary predicate does not introduce any new or different questions of safety and effectiveness.

- Marker materials. Materials for the marker component of the subject device are different than for the primary predicate device but are similar to the materials for the reference devices (SignalMark Breast Marker, HydroMARK Breast Biopsy Site Marker). Materials for the OneMark Breast Marker have undergone testing to ensure the marker is as safe and effective as the predicate markers (SAVI Scout Reflector, SignalMark Breast Marker, HydroMARK Breast Biopsy Site Marker).
- Marker dimensions. The marker for the subject device is smaller in size than the marker for the primary predicate device, but its dimensions are similar to the dimensions of the reference predicate marker (HydroMARK Breast Biopsy Site Marker). This difference with the primary predicate does not introduce any new or different questions of safety and effectiveness.
- Marker sterilization. Gamma radiation was used to achieve a SAL of 10^{-6} for the Marker, compared to ethylene oxide for the primary predicate. Gamma radiation method was also used for the reference device (SignalMark Breast Marker).

These technological differences have undergone testing to ensure the subject device is as safe and effective as the predicate device.

SUMMARY OF NON-CLINICAL TESTING

The following tests were performed to demonstrate safety based on current industry standards:

- Biocompatibility testing per ISO 10993-1
- Gamma radiation sterilization validation per ANSI/AAMI/ISO 11137-2
- Shelf-life validation testing
- Packaging validation testing per ISTA 2A-2011 and ASTM F2096-11
- Software testing per IEC 62304
- Electrical safety testing per IEC 60601-1 and IEC 60601-2-37
- EMC testing per IEC 60601-1-2
- Non-clinical performance bench testing
- GLP animal testing

The results of these tests indicate that OneMark is substantially equivalent to the predicate devices.

CONCLUSION

Based on the testing performed, including sterilization validation, packaging and shelf-life validation, biocompatibility, software validation, electrical safety, EMC testing, non-clinical performance bench testing, and GLP animal testing, it can be concluded that the subject device (OneMark Biopsy Site Marker — K241762) does not raise new issues of safety or effectiveness compared to the predicate device (Cianna Medical Scout Reflector and Scout System – K181007). The indications for use, technological characteristics, and performance characteristics for the proposed OneMark are assessed to be substantially equivalent to the predicate device.