August 14, 2019

View Point Medical, Inc.
% Michelle Rubin-Onur
Regulatory Specialist
AcKnowledge Regulatory Strategies, LLC
2251 San Diego Ave Suite B-257
San Diego, California 92110

Re: K190689
Trade/Device Name: SignalMark Breast Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: July 16, 2019
Received: July 17, 2019

Dear Michelle Rubin-Onur:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

David Krause, Ph.D.
Acting Division Director
Division of Infection Control and Plastic Surgery Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190689

Device Name
SignalMark Breast Marker

Indications for Use *(Describe)*
The SignalMark Breast Marker is intended to provide accuracy in marking a surigcal site and/or a biopsy location for visualization during surgical resection.

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.

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510(k) Summary

DATE PREPARED
July 16, 2019

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PROPRIETARY NAME OF SUBJECT DEVICE
SignalMark Breast Marker

COMMON NAME
Biopsy site marker

DEVICE CLASSIFICATION
Implantable clip (Product code NEU, Class II)
21 CFR 878.4300 Implantable clip

INDICATIONS FOR USE
The SignalMark Breast Marker is intended to provide accuracy in marking a surgical site and/or a biopsy location for visualization during surgical resection.

DEVICE DESCRIPTION
The SignalMark Breast Marker is a medical device used by a physician to percutaneously place a small implantable hydrogel marker in breast tissue to “mark” the location of the biopsy or surgical site. It is intended to be used on adults undergoing open surgical breast biopsy or percutaneous breast biopsy, in a surgical setting, such as a hospital or medical clinic with operating suites. The SignalMark Breast Marker consists of two components:

- Applicator: Component made of plastic and stainless steel that pushes the marker into the tissue.

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- Marker Pad: Component made of USP-grade porcine gelatin-based hydrogel with methylene blue-colored silicon dioxide microspheres. The marker aids in the visualization of tissue allowing surgeons to readily locate the biopsy site for subsequent tissue or tumor resection.

PREDICATE DEVICE IDENTIFICATION

SignalMark Breast Marker is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K060769	HydroMark Biopsy Site Marker / Biopsy Sciences, Inc.	✓
K180175	SignalMark Lung Biopsy Site Marker / View Point Medical, Inc.	(Reference device)

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for the SignalMark Breast Marker.

Patient-contacting material was subjected to biocompatibility testing in compliance with ISO 10993-1 *Biological evaluation of medical devices – Part 1: Evaluation and testing with a risk management process.*

The following tests were performed to demonstrate equivalence to the predicate device:

- Performance testing (Bench)
  - Visual Inspection of the Applicator
  - Applicator Deployment Test
  - Applicator Dimensional Inspection
  - Applicator Stroke Length Test
  - Applicator Compression Test
  - Applicator Tensile Test
  - Visual Inspection of the Marker Pad
  - Marker Pad Diameter
  - Marker Pad Hydration
  - Marker Pad Ultrasound Visual Test
  - Labeling wipe test with 70% IPA
  - Packaged Contents Verification
- Performance testing (Animal)
  - Biodistribution in rodents
  - Safety and efficacy in porcine
  - Biologic response in porcine

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EQUIVLANCE TO PREDICATE DEVICE

The SignalMark Breast Marker is substantially equivalent to the predicate device based on the information summarized here:

The subject device has the same intended use and uses similar materials as the device cleared in K060769; namely, both are meant to mark a biopsy location in breast tissue and both use an absorbable hydrogel that expands on fluid contact. Additionally, both devices are visible under ultrasound.

The subject device also has a similar design and dimensions and uses identical materials as the device cleared in K180175. Key technological characteristics of the subject device and reference device (K180175) remain identical; in particular the Applicator and chemical composition of the USP-grade porcine gelatin-based hydrogel Marker Pad with methylene blue-colored, silicon dioxide microspheres. The main difference is that the subject device is provided in two formats (three 1.0 cm pads or one 3.0 cm pad) whereas the reference device is only provided in one format (one 3.0 cm pad). This new format has been added to allow physicians more control over how they place the device in breast tissue, though the total volume of the implant remains the same as the device cleared in K180175.

CONCLUSION

Based on the testing performed, including biocompatibility and non-clinical performance testing (bench and animal), it can be concluded that the subject device does not raise new issues of safety or effectiveness compared to the predicate devices. The similar indications for use, technological characteristics, and performance characteristics for the proposed SignalMark Breast Marker are assessed to be substantially equivalent to the predicate devices.