December 7, 2018

ViewPoint Medical, Inc.
Thomas Kane
Vice President, Regulatory Affairs & Quality Assurance
1235 Puerta del Sol #600
San Clemente, California 92673

Re: K180175
Trade/Device Name: SignalMark Lung Biopsy Site Marker
Regulation Number: 21 CFR 878.4750
Regulation Name: Implantable Staple
Regulatory Class: Class II
Product Code: GDW
Dated: November 2, 2018
Received: November 6, 2018

Dear Thomas Kane:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cynthia Chang -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K180175

Device Name

SignalMark Lung Biopsy Site Marker

Indications for Use *(Describe)*

The SignalMark Lung Biopsy Site Marker is intended to provide accuracy in marking 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.

510(k) Summary
K180175

DATE PREPARED
December 6, 2018

MANUFACTURER AND 510(k) OWNER
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PROPRIETARY NAME OF SUBJECT DEVICE
SignalMark Lung Biopsy Site Marker

COMMON NAME
Biopsy site marker

DEVICE CLASSIFICATION
Staple, Implantable (Product code GDW, Class II)
21 CFR 878.4750 Implantable staple

INDICATIONS FOR USE
The SignalMark Lung Biopsy Site Marker is intended to provide accuracy in marking a biopsy location for visualization during surgical resection.

DEVICE DESCRIPTION
The SignalMark Lung Biopsy Site Marker is a medical device used by a physician to percutaneously place a small implantable hydrogel marker in lung tissue during a tissue biopsy to “mark” the location of the biopsy site. It is intended to be used on adults undergoing percutaneous lung biopsies, in surgical settings, such as hospitals or medical clinics with operating suites. The SignalMark Lung Biopsy Site Marker consists of two components:

- Applicator: Component made of plastic and stainless steel that pushes the marker into the tissue.
- Marker: 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 Lung Biopsy Site Marker is substantially equivalent to the following predicate:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*
K041331	Lung Biopsy Site Marker / Biopsy Sciences, LLC	✓
K071937	BonAlive granules and plates / Vivoxid, Ltd.	(Reference Device)
K110925	NovaBone MacroPor-Si+ – Bioactive Synthetic Bone Graft	(Reference Device)

SUMMARY OF NON-CLINICAL TESTING

No FDA performance standards have been established for SignalMark Lung Biopsy Site Marker.

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

The following performance testing was completed in order 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 Length
  - Marker Pad Hydration
  - Marker Pad Ultrasound Visual Test
  - Wipe test with 70% IPA
  - Packaged Contents Verification
- Performance testing (Animal)
  - Biodistribution in rodents

- Safety and efficacy in porcine
- Biologic response in porcine

EQUIVALENCE TO PREDICATE DEVICE

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

The subject device uses similar or identical materials as the devices cleared in K041331, K071937, and K110925. The subject device has the same intended use, intended population, and use environments as the predicate device cleared in K041331. The subject device has similar technological characteristics to the device cleared in K041331. Unlike the predicate device, the SignalMark Lung Biopsy Site Marker uses silicon dioxide microspheres and USP grade porcine gelatin-based hydrogel in the marker. These technological characteristics have undergone bench and animal testing to ensure the device is substantially equivalent to the predicate.

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 device. The similar technological characteristics and performance characteristics for the proposed SignalMark Lung Biopsy Site Marker device are assessed to be substantially equivalent to the predicate device.