July 19, 2019

Augmenix, Inc.
% Mr. Marcus Garcia
Principal Regulatory Affairs Specialist
201 Burlington Road, North Building
BEDFORD MA 01730

Re: K182971
Trade/Device Name: SpaceOAR Vue Hydrogel
Regulation Number: 21 CFR 892.5725
Regulation Name: Absorbable Perirectal Spacer
Regulatory Class: Class II
Product Code: OVB
Dated: June 13, 2019
Received: June 14, 2019

Dear Mr. Garcia:

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,

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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)*
K182971

Device Name
Space OAR Vue Hydrogel

Indications for Use *(Describe)*
SpaceOAR Vue Hydrogel is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR Vue Hydrogel to reduce the radiation dose delivered to the anterior rectum. The SpaceOAR Vue Hydrogel is composed of biodegradable material and maintain space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

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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6 510(k) Summary

Date: October 25, 2018

I. SUBMITTER

Augmenix, Inc.
201 Burlington Road
Bedford, MA 01730

Establishment Registration Number: 3008550999

Contact Person: Marcus Garcia, RAC

Phone: 781-541-4360
email: mgarcia@augmenix.com

II. DEVICE

Device Trade Name: SpaceOAR Vue™ Hydrogel, Model Number: SV-2101
Device Common or Usual Name: Absorbable Perirectal Spacer
Device Classification Name: Hydrogel Spacer
Device Classification: Class II
Device Product Code: OVB
Device Review Panel: Radiology

III. PREDICATE DEVICE

Predicate Device Trade Name: SpaceOAR® Hydrogel System
Cleared for Marketing Under: DEN140030 and K181465.

Reference device: TraceIT® Tissue Marker K151998 and K121964.

IV. DEVICE DESCRIPTION

The SpaceOAR Vue Hydrogel consists of components for the preparation of a synthetic, absorbable hydrogel spacer and a delivery mechanism provided in a sterile, single use package. The SpaceOAR Vue Hydrogel is a synthetic, absorbable polyethylene glycol (PEG)-based hydrogel that upon injection creates a space that temporarily positions the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of the perirectal spacer to reduce the radiation dose

delivered to the anterior rectum. SpaceOAR Vue Hydrogel is completely synthetic with no animal or human derived components. It is composed of biodegradable material and maintains space for the entire course of prostate radiotherapy treatment (approximately 3 months) and is completely absorbed by the patient's body over time (about 6 months).

The SpaceOAR Vue Hydrogel consists of two syringes containing the PEG Precursor solution and the Accelerator solution (a buffered salt solution). The Precursor solution is formed by the user through the reconstitution of PEG powder with a Diluent (Trilysine buffer) solution (that is provided in a third syringe). The Accelerator solution is provided ready for use. The Syringes filled with the Precursor solution and the Accelerator solution are assembled with other applicator components, including a Y-connector for mixing the Precursor and Accelerator, and a needle to facilitate delivery of the hydrogel by injection to the tissue located between the anterior rectal wall and the prostate.

V. INDICATIONS FOR USE

SpaceOAR Vue Hydrogel is intended to temporarily position the anterior rectal wall away from the prostate during radiotherapy for prostate cancer and in creating this space it is the intent of SpaceOAR Vue Hydrogel to reduce the radiation dose delivered to the anterior rectum. The SpaceOAR Vue Hydrogel is composed of biodegradable material and maintains space for the entire course of prostate radiotherapy treatment and is completely absorbed by the patient's body over time.

The Indications for Use Statement for the subject SpaceOAR Vue Hydrogel is identical to the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The underlying technological characteristics of the subject SpaceOAR Vue Hydrogel and the predicate device are identical. Both devices are a system that facilitates the implantation of 10mL biodegradable PEG hydrogel between the anterior rectal wall and prostate prior to radiotherapy. This temporarily creates space between the anterior rectal wall and prostate during radiotherapy. The PEG hydrogel is broken down through hydrolysis and excreted from the body through renal filtration. The key difference between the SpaceOAR Vue and the predicate device is the additional feature of radiopacity. SpaceOAR Vue introduces the added benefit of radiopacity for CT and CBCT visibility. All other features of the devices remain the same.

VII. PERFORMANCE DATA

Applicable verification and validation testing was performed as required by the Augmenix design control process. The following performance data were provided in support of the substantial equivalence determination:

- Sterilization Validation
- Modulus Testing
- Gel Volume (Swell) Testing
- Gel Time Testing
- Pot Life Testing
- Usability Testing
- Biocompatibility Testing
- Preclinical Testing

The subject device has met the same device specifications as the predicate device; therefore, clinical data were not required to support a determination of substantial equivalence.

Summary

Verification and/or validation of the subject device was completed and confirmed that the subject SpaceOAR Vue Hydrogel meets the same finished device specification as the predicate SpaceOAR® Hydrogel System.

VIII. CONCLUSION

The subject SpaceOAR Vue Hydrogel met all acceptance criteria for verification and/or validation. This demonstrates that the subject device performance is equivalent to the predicate device and that the subject device performance supports the requirements of the device intended use.