Viscus Biologics, LLC
% Mr. Dave Yungvirt
CEO
Third Party Review Group, LLC
25 Independence Blvd.
WARREN NJ 07059

March 4, 2019

Re: K190155
Trade/Device Name: FibermarX Radiopaque Tissue Marker
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: Class II
Product Code: IYE
Dated: February 18, 2019
Received: February 19, 2019

Dear Mr. Yungvirt:

This letter corrects our substantially equivalent letter of February 27, 2019.

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,

For

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

Device Name
FibermarX™ Radiopaque Tissue Marker

Indications for Use *(Describe)*
FibermarX™ Radiopaque Tissue Marker is intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization. In addition, the markers are indicated in situations where tissue needs to be marked for future medical procedures such as IMRT/IGRT.

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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"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."

SECTION 5
510(K) SUMMARY TRADITIONAL 510(k)

Submitter- Manufacturer: Viscus Biologics, LLC,
10000 Cedar Avenue
Cleveland, OH 44106, USA.
Tel: +1 216 744 – 2740

Submitted by and Contact Person

Justin Baker
Viscus Biologics, LLC
10000 Cedar Avenue
Cleveland, OH 44106
Tel: +1 216 744 – 2744

CONTACT PERSON:	Justin Baker
DATE PREPARED:	January 28, 2019
TRADE NAME:	FibermarX™ Radiopaque Tissue Marker
COMMON NAME:	Implantable Radiographic Tissue Marker
CLASSIFICATION NAME:	Accelerator, Linear, Medical
REGULATION:	21 CFR 892.5050
PRODUCT CODE:	IYE, NEU
CLASS:	Class II

PREDICATE DEVICES:

CIVCO Medical Suture-Type Marker (primary predicate)(K071614)

REFERENCE DEVICE(s):

Viscus Biologics Radiopaque Tissue Marker (K170026)

INDICATIONS FOR USE:

The FibermarX™ Radiopaque Tissue Marker is intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization. In addition, the markers are indicated in situations where tissue needs to be marked for future medical procedures such as IMRT/IGRT.

DEVICE DESCRIPTION:

The device is a sterile, single-patient-use, barium sulfate infused non-absorbable polymer monofilament that is visible on standard radiographs (x-ray, CT, mammography). FibermarX™ is passed through soft tissue and tied into place during open, percutaneous, or arthroscopic/laparoscopic/endoscopic procedures and standard surgeon's knots or a continuous running outline are used to quickly mark the soft tissue for subsequent imaging or for radiotherapy target localization. There are absolutely no changes in materials or design in the subject device from the reference device K170026.

TECHNOLOGICAL CHARACTERISTICS:

The FibermarX™ Radiopaque Tissue Marker is identical to Radiopaque Tissue Marker (K170026) except the indications for use are in accordance with CIVCO Medical Suture-type Marker (K071614). The FibermarX™ Radiopaque Tissue Marker is substantially equivalent to the predicate and reference devices in terms of physical and technical characteristics. The subject and predicate devices are composed of a radiopaque metal element and are either embedded within or attached to a polymer monofilament element and have identical intended use.

	FibermarX™ Radiopaque Tissue Marker	**CIVCO Medical suture-type marker** (K071614, IYE) (Primary Predicate)	**Radiopaque Tissue Marker** (K170026, NEU, reference)
Overall Technological Characteristics	Radiographically visible metal-based permanent marker element(s) closely attached to a polymer	SAME	SAME
Principle of Operation	Marker is positioned into tissue site for radiographic visualization of tissue site	SAME	SAME
Visualization Compatibility	Mammography X-ray CT	(Mammography)-*unknown* X-Ray CT	SAME
Materials of Construction	Barium sulfate, nonabsorbable polymer (monofilament)	Gold, bioabsorbable polymer (suture monofilament)	SAME
Typical Anatomical Treatment Site	Soft Tissue, including breast	SAME	SAME
Method of Marker Deployment	Manual, open surgical or laparoscopically	Manual, open surgical	SAME
Marker Stability	Sutured in place (knots or running outline)	Sutured in place	SAME

Provided Sterile	Yes	Yes	Yes
Sterilization Method	EO	Unknown	EO

NON-CLINICAL TESTING BASIS FOR SUBSTANTIAL EQUIVALENCE:

We performed a Failure Mode Effects Analysis (FMEA) on the Radiopaque Tissue Marker when used in accordance with the IYE indications for use. Extractables from Radiopaque Tissue Marker were analyzed using Gas Chromatograph-Mass Spectrometry, Liquid Chromatograph-Mass Spectrometry, and Inductively Coupled Plasma-Mass Spectrometry and a toxicological risk assessment was performed that along with ISO 10993 biocompatibility testing (cytotoxicity, Intracutaneous irritation, sensitization, intramuscular implantation, pyrogenicity, and acute systemic toxicity) showed that the subject device is biocompatible and non-pyrogenic. Sterilization resistance and bioburden testing was performed to determine the proper ethylene oxide parameters for achieving a sterilization assurance level of 10^{-6} in order to ensure sterility. CT/x-ray radiographic imaging at low, medium, and high doses and mammography of implanted subject and predicate devices was performed to show substantially equivalent radiographic visualization of the tissue markers. Packaging validation and post shelf-life performance was also tested.

Additional testing evaluating the FibermarX™ Radiopaque Tissue Marker when used for radiotherapy target localization was performed and the impact of the radiation on the mechanical properties, visibility, and cytotoxicity of the device was evaluated. Results showed no negative impacts that would prevent the FibermarX™ Radiopaque Tissue Marker from substantially equivalent safe and effective use for the proposed indications for use.

CONCLUSION

Viscus Biologics, LLC believes that the FibermarX™ Radiopaque Tissue Marker as described in this submission and as evidenced by the results of testing and the similar technological characteristics and intended use described above, does not raise any new or significant questions of safety and efficacy and is substantially equivalent to existing legally marketed devices.