DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 2, 2017

Viscus Biologics, LLC
Ms. Leslie Clark
Director, Quality
10000 Cedar Ave
Cleveland, Ohio 44106

Re: K170026
Trade/Device Name: Radiopaque Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: May 18, 2017
Received: May 19, 2017

Dear Ms. Clark:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S3

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170026

Device Name
Radiopaque Tissue Marker

Indications for Use *(Describe)*
The Radiopaque Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures

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

Submitter- Manufacturer: Viscus Biologics, LLC,
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Submitted by and Contact Person

Rebecca Clark
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10000 Cedar Avenue
Cleveland, OH 44106
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CONTACT PERSON:	**Rebecca Clark**
DATE PREPARED:	**December 29, 2016**
TRADE NAME:	**Radiopaque Tissue Marker**
COMMON NAME:	Implantable Radiographic Marker
CLASSIFICATION NAME:	Implantable Clip
REGULATION	21 CFR 878.4300
PROCODE and CLASS	General and Plastic Surgery, NEU, Class II

PREDICATE DEVICE:

Cassi Beacon Tissue Marker (K140835)

REFERENCE DEVICE(s):

Focal Therapeutics BioZorb Marker (K143484)

INDICATIONS FOR USE:

The Radiopaque Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.

DEVICE DESCRIPTION:

The device is a sterile, single-patient-use, barium sulfate infused polypropylene suture that is radiopaque using standard radiographs (x-ray, mammography). The device is placed into soft tissue sites during open, percutaneous, or endoscopic procedures and standard surgeon's knots are tied to quickly and inexpensively mark the soft tissue so that the integrity and location of the marked soft tissue can be evaluated.

TECHNOLOGICAL CHARACTERISTICS:

The Radiopaque Tissue Marker is substantially equivalent to the Cassi Beacon Tissue Marker by Scion Medical Technologies (K140835) in terms of intended use/indications for use, composition, biocompatibility, sterility and use, and performance. The predicate and subject device have identical indications for use. The subject and predicate device both utilize a barium sulfate ($BaSO_4$) composition to achieve radiopacity that is infused into a polymer base. The Cassi Beacon Tissue Marker uses barium sulfate as a radiocontrast agent with polyetherketoneketone (PEKK) as a polymer base, while the Radiopaque Tissue Marker uses barium sulfate with polypropylene as its polymer base due to polypropylene's ability to be extruded and processed to increase tensile strength, which is required for placement and knot tying. The subject device underwent biocompatibility testing according to ISO 10993. Both devices are supplied as sterile, single patient use. While the predicate device uses a specific delivery system as part of the device, the subject device can be used with any general suture passer or may be used without a suture passer depending on the physician's preference and the tissue to be marked. This difference is not critical to the intended use and does not affect the safety and effectiveness of the device.

NON-CLINICAL TESTING BASIS FOR SUBSTANTIAL EQUIVALENCE:

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.

CONCLUSION

Viscus Biologics, LLC believes that the Radiopaque Tissue Marker as described in this submission and as evidenced by the results of testing and the similar technological characteristics described above, does not raise any new or significant questions of safety and efficacy and is substantially equivalent to the predicate Scion Medical technologies, LLC Cassi Beacon Tissue Marker (K140835).