Focal Therapeutics, Inc.
% Mr. George Hermann
President
1010 Stewart Drive
SUNNYVALE CA 94085

November 9, 2017

Re: K171467
Trade/Device Name: BioZorb Marker GOLD / LP Marker GOLD
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: October 18, 2017
Received: October 19, 2017

Dear Mr. Hermann:

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.

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.

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,

Robert Ochs

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)*
K171467

Device Name
BioZorb Marker GOLD / LP Marker GOLD

Indications for Use *(Describe)*
The Marker is intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization.

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

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT:	Focal Therapeutics
DATE PREPARED:	June 21, 2017
CONTACT PERSON:	George Hermann Focal Therapeutics 1010 Stewart Drive Sunnyvale, CA 94085 Phone: 408.962.7010 Fax: 408.962.7020
TRADE NAME:	BioZorb Marker *GOLD* / LP Marker *GOLD*
COMMON NAME:	Implantable Radiographic Fiducial Marker
CLASSIFICATION NAME:	Accelerator, Linear, Medical, 21 CFR 892.5050
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE:	IYE
PREDICATE DEVICES:	Civco Suture-type Marker (K071614) (Primary Predicate) Focal Therapeutics BioZorb Marker (K143484) and BioZorb LP Marker (K152070) BiomarC Fiducial Marker (K132708, K110772)

Substantially Equivalent To:
The BioZorb Marker *GOLD*/ LP Marker *GOLD* is substantially equivalent in intended use, principal of operation and technological characteristics to the Civco Suture-type Marker (K071614), Focal Therapeutics BioZorb Marker (K143484), BioZorb LP Marker (K152070), and the BiomarC Fiducial Marker (K132708, K110772).

Description of the Device Subject to Premarket Notification:

The BioZorb Marker *GOLD* / LP Marker *GOLD* is an implantable radiopaque marker comprised of a bioabsorbable component and a permanent component.

The BioZorb Marker *GOLD* / LP Marker *GOLD* is provided sterile for single use and is implantable.

Indication for Use:

The Marker is intended to be implanted into the body to accurately visualize and constitute the reference frame for stereotactic radiosurgery and radiotherapy target localization.

Technical Characteristics:

The BioZorb Marker *GOLD* / LP Marker *GOLD* has similar physical and technical characteristics to the predicate devices. In particular, the Marker and the predicate devices are comprised of the same primary components and the component materials are substantially equivalent.

	Focal BioZorb Marker *GOLD* / LP Marker *GOLD*	**Civco Medical Suture-type Marker (K071614, IYE)** (Primary Predicate)	**Focal BioZorb Marker (K143484) & BioZorb LP Marker (K152070) (NEU)**	**Carbon Medical Technologies BiomarC Fiducial Marker (K132064, IYE, K110772, NEU)**
Overall Technological Characteristics	Radiographically visible permanent marker element(s) in bioabsorbable polymer spacer	SAME	SAME	SAME
Principle of Operation	Marker is positioned into tissue site for radiographic visualization of tissue site	SAME	SAME	SAME
Visualization Compatibility	Mammography Ultrasound X-Ray CT MRI	X-Ray CT (presumed)	SAME	Mammography Ultrasound X-Ray MRI Fluoroscopy kV CT
Materials of Construction	Gold, bioabsorbable polymer (spacer)	Gold, bioabsorbable polymer (suture)	Titanium, bioabsorbable polymer (spacer)	Pyrolytic carbon coated zirconium oxide
Overall Device Length	2-4 cm	>5 cm (with suture)	2-5 cm	2 mm x 4 mm
Typical Anatomical Treatment Site	Soft tissue including breast	breast	SAME	SAME
Method of Marker Deployment	Manual, open surgical	SAME	SAME	Manual, percutaneous
Marker Stability	Sutured in place	SAME	SAME	Tissue retention
Provided sterile	Yes	Yes	Yes	Yes
Steriliz. method	Radiation	Unknown	SAME	EO

Performance Data:

All necessary verification and validation testing has been performed for the BioZorb Marker *GOLD* / LP Marker *GOLD* to assure substantial equivalence to the predicate devices and demonstrate the device performs as intended.

Performance data included:

- Simulated Use
- Device Integrity
- Imaging Assessment
- MR Compatibility

The BioZorb Marker *GOLD* / LP Marker *GOLD* met all specified criteria and did not raise new safety or performance questions.

Basis for Determination of Substantial Equivalence:

Upon reviewing the safety and efficacy information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the BioZorb Marker *GOLD* / LP Marker *GOLD* is determined by Focal Therapeutics to be substantially equivalent to existing legally marketed devices.