DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 26, 2015

Focal Therapeutics
Mr. George Hermann
President
4370 Alpine Road #101
Portola Valley, California 94028

Re: K152070
Trade/Device Name: BioZorb LP Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: July 24, 2015
Received: July 27, 2015

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.

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" (21CFR 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 yours,

David Krause -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K152070

Device Name
BioZorb LP Marker

Indications for Use *(Describe)*
The BioZorb LP Marker is indicated for radiographic marking of sites in soft tissue.

In addition, the Marker is indicated in situations where the soft tissue site needs to be marked for future medical 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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1. 510(k) Summary

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

APPLICANT:	Focal Therapeutics
DATE PREPARED:	08/14/15
CONTACT PERSON:	George Hermann Focal Therapeutics 4370 Alpine Rd. #101 Portola Valley, CA 94028 Phone: 650.530.2394 Fax: 650.530.2397
TRADE NAME:	BioZorb™ LP Marker
COMMON NAME:	Implantable Radiographic Marker
CLASSIFICATION NAME:	Implantable Clip, 21 CFR, 878.4300
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	NEU
PREDICATE DEVICES:	(primary) BioZorb Marker (K143484)

Substantially Equivalent To:
The modified BioZorb Marker (BioZorb LP Marker) is substantially equivalent in intended use, principal of operation and technological characteristics to the BioZorb Marker cleared under premarket notification K143484.

Description of the Device Subject to Premarket Notification:
The BioZorb LP Marker is an implantable radiopaque marker used to facilitate visualization of a soft tissue site. The BioZorb LP Marker is comprised of a bioabsorbable PLA (polylactic acid) component which resorbs completely in 1 year or more and a permanent component (titanium). The BioZorb LP Marker is provided sterile for single use and is implantable.

Indication for Use:
The BioZorb LP Marker is indicated for radiographic marking of sites in soft tissue. In addition, the Marker is indicated in situations where the soft tissue site needs to be marked for future medical procedures.

Technical Characteristics:
The modified BioZorb Marker has the same or similar physical and technical characteristics as the predicate device. Low profile markers have been added to the BioZorb product family.

	Subject device	Predicate device
	BioZorb Marker, Modified	**BioZorb Marker (K143484)**
Overall Technological Characteristics	SAME	Radiographically visible permanent marker element(s) in bioabsorbable polymer spacer
Principle of Operation	SAME	Marker is positioned into tissue site for radiographic visualization of tissue site
Visualization Compatibility	SAME	Mammography Ultrasound X-Ray CT MR
Device Shape	Low Profile (circular, oval)	Spiral
Materials of Construction	SAME	Titanium (marker clip), bioabsorbable polymer (spacer)
Overall Device Length	SAME	2-5 cm
Typical Anatomical Treatment Site	SAME	Soft tissue including breast
Method of Marker Deployment	SAME	Manual, open surgical
Marker Stability	SAME	Sutured in place
Provided sterile	SAME	Yes
Sterilization method	SAME	Radiation

Performance Data:
All necessary testing has been performed for the modified BioZorb Marker to assure substantial equivalence to the predicate device and demonstrate the device performs as intended.

The device design was qualified through the following tests:

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

The modified BioZorb Marker met all specified criteria and did not raise new safety or performance questions.

Basis for Determination of Substantial Equivalence:
The Indication/Intended Use and the fundamental scientific technology of the modified device have not been changed and are the same as those described in the unmodified predicate device. The modified BioZorb Marker device is found to have a safety and effectiveness profile that is the same as the predicate device and is determined by Focal Therapeutics to be substantially equivalent to the BioZorb Marker (K143484).