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 29, 2015

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

Re: K143484
Trade/Device Name: BioZorb Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: May 22, 2015
Received: May 28, 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)*
K143484

Device Name
BioZorb Marker

Indications for Use *(Describe)*
The BioZorb 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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6. 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 23, 2015
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 Marker
COMMON NAME:	Implantable Radiographic Marker
CLASSIFICATION NAME:	Implantable Clip, 21 CFR, 878.4300, 892.5050
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE	NEU
PREDICATE DEVICES:	Mixed Media Marker (K102506) Civco Suture-type Marker [reference predicate] (K071614) Focal Therapeutics BioZorb Tissue Marker (K113202)

Substantially Equivalent To:

The BioZorb Marker is substantially equivalent in intended use, principal of operation and technological characteristics to the Mixed Media Marker (K102506), Suture-type Marker (K071614) and the BioZorb Tissue Marker (K113202).

Description of the Device Subject to Premarket Notification:

The BioZorb Marker is an implantable radiopaque marker comprised of a bioabsorbable PLA (polylactic acid) component which resorbs completely in 1 or more years and a permanent component (titanium).

The BioZorb Marker is provided sterile for single use and is implantable.

Indication for Use:

The BioZorb Marker is indicated for radiographic marking of sites in soft tissue.

Section 6 510(k) Summary

In addition, the Marker is indicated in situations where the soft tissue site needs to be marked for future medical procedures.

Technical Characteristics:

The BioZorb Marker has similar physical and technical characteristics to the predicate devices, as illustrated in the table below.

	Subject device	**Primary Predicate**	**Primary Predicate**	**Reference Predicate**
	Focal BioZorb Marker	**Focal BioZorb Tissue Marker (K113202)**	**Cortex Mixed Media Marker (K102506)**	**Civco Medical Suture-type Marker (K071614)**
Overall Technological Characteristics	Radiographically visible permanent marker element(s) in bioabsorbable polymer spacer	SAME	Radiographically visible permanent marker element(s) with or without polymer	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	SAME	SAME	X-Ray CT (presumed)
Materials of Construction	Titanium, bioabsorbable polymer (spacer)	SAME	Gold, titanium or PEEK polymer, stainless steel	Gold, bioabsorbable polymer (suture)
Overall Device Length	2-5 cm	SAME	1 mm x ~ 20 mm	>5 cm (with suture)
Typical Anatomical Treatment Site	Soft tissue including breast	SAME	SAME	breast
Method of Marker Deployment	Manual, open surgical	SAME	Manual, percutaneous	SAME
Marker Stability	Sutured in place	Tissue retention	Tissue retention	SAME
Provided sterile	Yes	Yes	Yes	Yes
Steriliz. method	Radiation	SAME	Unknown	Unknown

Performance Data:

Performance data included:

- Pyrogenicity, LAL (USP Pharmacopeia <85>)
- MR compatibility (ASTM 2052-14, ASTM F2213-06, ASTM 2182-11a, ASTM F2119-07) and,
- Shelf life testing (ASTM D4169, ASTM F2096, ASTM F88/F88M, ASTM F1980, ISO 11607-1).

The Focal BioZorb Marker performance is identical to the predicate device (K113202).

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 is determined by Focal Therapeutics to be substantially equivalent to existing legally marketed devices.