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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:	February 28, 2012
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™ Tissue Marker
COMMON NAME:	Implantable Radiographic Marker
CLASSIFICATION NAME:	Implantable Clip, 21 CFR, 878.4300
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE:	NEU
PREDICATE DEVICES:	Hologic/Suros Tissue Site Marking System (K062528, K072913); Bard/SenoRx GelMark Ultra (K011402); Devicor/Artemis CorMARK Marker (K032217)

Substantially Equivalent To:

The Focal Therapeutics BioZorb™ Tissue Marker is substantially equivalent in intended use, principal of operation and technological characteristics to the Hologic/Suros Tissue Site Marking Systems (K062528, K072913), the Bard/SenoRx GelMark Ultra (K011402), and the Devicor/Artemis CorMARK (K032217) devices.

Description of the Device Subject to Premarket Notification:

The BioZorb Tissue Marker is an implantable radiopaque marker used to facilitate visualization of a soft tissue site. The BioZorb Tissue Marker is comprised of a bioabsorbable component and a permanent component.

The BioZorb Tissue Marker is provided sterile for single use and is disposable.

Indication for Use:

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

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Technical Characteristics:

The BioZorb™ Tissue Marker has similar physical and technical characteristics to the predicate devices. In particular the BioZorb Tissue Marker and the predicate devices are comprised of the same primary components and the component materials are substantially equivalent.

Performance Data:

All necessary verification and validation testing has been performed for the BioZorb Tissue Marker to assure substantial equivalence to the predicate devices, including image based verification.

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

FEB 28 2012

Re: K113202
Trade/Device Name: BioZorb™ Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: February 22, 2012
Received: February 23, 2012

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K113202

5. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: BioZorb™ Tissue Marker

Indications for Use:

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

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

OR

Prescription Use __X__
(Per 21 CFR 801 Subpart D)

Over-The-Counter Use_____
(Per 21 CFR 801 Subpart C)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113202