September 26, 2019

Focal Therapeutics
Dhaval Saraiya
Principal Regulatory Affairs Specialist
1010 Stewart Drive
Sunnyvale, California 94085

Re: K192371
Trade/Device Name: BioZorb SP Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: August 29, 2019
Received: August 30, 2019

Dear Dhaval Saraiya:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Cindy Chowdhury, Ph.D., M.B.A.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K192371

Device Name
BioZorb® SP Marker

Indications for Use *(Describe)*
The BioZorb SP 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.

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

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510(k) SUMMARY

Date: August 29, 2019

I. SUBMITTER

Focal Therapeutics
A Hologic Company
1010 Stewart Drive
Sunnyvale, CA 94085

Contact person: Dhaval Saraiya
Phone: 508.263.8823
Email: Dhaval.saraiya@hologic.com

II. DEVICE

Name of the device: BioZorb® SP Marker
Common or usual name: Implantable Radiographic Marker
Regulation name: Implantable Clip
Regulation Number: 21 CFR 878.4300
Product Code: NEU
Classification: Class II
Panel: General and Plastic Surgery

III. PREDICATE DEVICE

BioZorb Marker (K143484)
BioZorb LP Marker (K152070)
These cleared products have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The BioZorb SP Marker is an implantable radiopaque marker used to facilitate visualization of a soft tissue site. The BioZorb SP 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 SP Marker is provided sterile for single use and is implantable.

V. INDICATIONS FOR USE

The BioZorb SP 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 BioZorb SP Marker has similar physical and technical characteristics as the predicate devices. The shape of the implant is identical to the current BioZorb (K143484) and the titanium clips (i.e. markers) are identical to those cleared in the BioZorb LP Marker (K152070).

VI. PERFORMANCE DATA

All necessary testing has been performed for the subject BioZorb SP Marker to ensure substantial equivalence to the predicate device and demonstrate the device performs as intended.

Performance data with regards to imaging assessment and MR compatibility are provided in support of the substantial equivalence.

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

VII. BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The Indication/Intended Use and the fundamental scientific technology of the subject device have not been changed and are the same as those described in the predicate devices. The BioZorb SP Marker device is found to have a safety and effectiveness profile that is substantially equivalent to the predicate devices.