June 6, 2018

Sonavex, Inc.
Mr. David Narrow
Chief Executive Officer
2835 O'Donnell Street, Suite 200
Baltimore, Maryland 21224

Re: K180621
Trade/Device Name: EchoMark, EchoMark LP
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: March 7, 2018
Received: March 9, 2018

Dear Mr. Narrow:

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 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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180621

Device Name
EchoMark and EchoMark LP

Indications for Use *(Describe)*
The EchoMark and EchoMark LP are indicated for radiographic marking of sites in soft tissue.

In addition, the EchoMark and EchoMark LP are indicated for situations where a 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Date Prepared: March 6, 2018

Applicant:
Sonavex, Inc.
2835 O'Donnell Street, Suite 200
Baltimore, MD 21224

Primary Contact Person:

David Narrow
Chief Executive Officer
Sonavex, Inc.
2835 O'Donnell Street, Suite 200
Baltimore, MD 21224
Phone: (443) 862-2003
Email: dnarrow@sonavex.com

Secondary Contact Person:

Devin O'Brien-Coon
President
Sonavex, Inc.
2835 O'Donnell Street, Suite 200
Baltimore, MD 21224
Phone: (443) 625-6201
Email: dcoon@sonavex.com

Trade Name: EchoMark™
EchoMark LP™

Common Name: Implantable Radiographic Marker

Classification Name: Implantable Clip, 21 CFR 878.4300

Device Classification: Class II

Product Code: NEU

Predicate Device: K152070, BioZorb LP Marker

Reference Device: K112267, Polyganics Neurolac Nerve Guide

Substantially Equivalent to:

The EchoMark and EchoMark LP are substantially equivalent in intended use, principle of operation and technological characteristics to the BioZorb LP Marker cleared under premarket notification K152070.

Description of the Device Subject to Premarket Notification:

The EchoMark and EchoMark LP are implantable ultrasound-visible markers used to facilitate visualization of a soft tissue site. The EchoMark and EchoMark LP are

comprised of 70:30 poly(L-lactide-co-caprolactone) (PLC) which resorbs completely in one year or more. The EchoMark LP (low profile) is identical but smaller in size than the EchoMark. Both have identical performance and technological characteristics. The EchoMark and EchoMark LP are provided sterile and are single use devices. The EchoMark material is entirely polymeric and therefore has no clinically relevant diamagnetic or ferromagnetic potential. This device is MR safe.

Indications for Use:
The EchoMark and EchoMark LP are indicated for radiographic marking of sites in soft tissue. In addition, the EchoMark and EchoMark LP are indicated for situations where a soft tissue site needs to be marked for future medical procedures.

Technical Characteristics Compared to Predicate Device:
The proposed predicate device for the EchoMark and EchoMark LP is the BioZorb LP Marker (K152070) manufactured by Focal Therapeutics. Sonavex has identified BioZorb LP as the predicate device because the devices share the same indications for use and identical or similar technological characteristics including principles of operation, compatibility with ultrasound, device size, polymeric materials, bioabsorption time and sterilization method.

Sonavex also used a reference device to support the material of the EchoMark and EchoMark LP which allows FDA to evaluate the proposed scientific methods for assessing this type of device material in a similar anatomic space (in addition to ISO 10993 biocompatibility testing). The reference device also shares certain technological similarities. The Neurolac Nerve Guide (Polyganics BV; K112267) is made from poly(lactide-*co*-caprolactone), which is the same material as the EchoMark and EchoMark LP. The Neurolac is also of similar size and is placed in surgical sites.

The EchoMark and EchoMark LP are indicated for radiographic marking of sites in soft tissue. The BioZorb LP Marker is also indicated for radiographic marking of sites in soft tissue. The EchoMark and EchoMark LP and the BioZorb LP are indicated for situations where the soft tissue site needs to be marked for future medical procedures. The markers are each positioned into a treatment site during a procedure and serve as passive imaging contrasts to the surrounding tissue for the purposes for radiographic visualization of the site at a later timepoint.
The BioZorb LP Marker and EchoMark/EchoMark LP are designed to mark treatment sites in soft tissue, which typically contains some combination of muscle, fat, fascia, and vessels. Anatomical treatment sites are identical.

The difference in indications for use between the EchoMark/EchoMark LP and BioZorb LP predicate does not constitute indications that create a new intended use. The EchoMark and EchoMark LP have the same intended use.

Technological characteristics between the EchoMark/EchoMark LP and the BioZorb LP are similar with some differences which were addressed with performance data. Differences include visualization compatibility as both the EchoMark/EchoMark LP and BioZorb LP Markers are radiographically visible markers composed of a bioabsorbable material, however, the BioZorb LP Marker also contains permanent titanium components that offer visibility under X-ray, CT, and MRI. The EchoMark/EchoMark LP

does not contain the titanium clips, and is intended to be visualized by ultrasound, a subset of the radiographic modalities available. Performance data was provided which evaluated this difference and found it did not impact substantial equivalence.

Both the EchoMark/EchoMark LP and the BioZorb LP Marker are low profile but there are differences in shape. Performance data was provided which addressed this difference and found that it did not impact substantial equivalence.

The EchoMark and EchoMark LP are radiographically visible markers composed solely of a bioabsorbable polymer: poly-lactide-*co*-caprolactone. The BioZorb LP Marker is a radiographically visible marker composed of a bioabsorbable poly-lactide polymer that has similar technological characteristics. The BioZorb LP Marker is made from the same lactide polymer without caprolactone. To establish equivalency of the device materials, a reference device, Polyganics' Neurolac Nerve Guide (K112267) was selected. The EchoMark/EchoMark LP and reference product, Neurolac Nerve Guide, are both made of poly-lactide-co-caprolactone.

The EchoMark/EchoMark LP and BioZorb LP Marker degrade within 1 year or more. Performance testing was completed to confirm bioabsorption time compared to the predicate device. The EchoMark/EchoMark LP is sterilized via ethylene oxide and BioZorb LP Marker is sterilized via gamma irradiation. Testing for ethylene oxide residuals has been performed and shows that residuals do not exceed acceptable limits.

The provided comparison of the specifications and associated device testing demonstrates the functional equivalence of the products. The differences discussed do not raise new issues of safety and effectiveness.

Therefore, the EchoMark and EchoMark LP are substantially equivalent to the predicate device.

Safety and Performance Data:
All necessary testing has been performed for the EchoMark and EchoMark LP to assure substantial equivalence to the predicate device and reference material and demonstrate that the device performs as intended.

The following ISO 10993 biocompatibility and safety testing was performed on the EchoMark device. Results from the tests indicate that the device is non-toxic, non-sensitizing, non-mutagenic and non-irritating therefore biocompatible for its intended use:

- Cytotoxicity
- Sensitization
- Irritation/ Intracutaneous Reactivity
- Acute Systemic Toxicity
- Pyrogenicity
- Genotoxicity
- Subacute/Subchronic Toxicity with Histologic Evaluation to confirm Safety (GLP Swine Testing)

Performance testing, Bench: Successful completion of the following tests confirmed that risk controls were properly implemented, and design outputs meet design inputs and device is suitable for its intended use:

- ISO 11135 Sterility testing validated to SAL of 10^{-6}
- ISO 11607-1 Packaging validation – distribution simulation
- Bench Suturability and Suture Retention
- Labeling verification
- Geometric analysis of EchoMark and EchoMark LP
- *In vitro* EchoMark and EchoMark LP degradation study

Performance testing, Animal (GLP Swine) and Cadaver:

- Ultrasound Visibility and Orientation Verification
- Ultrasound Echogenicity
- Ultrasound Accelerated Aging Echogenicity
- Suturability Timing Study
- Tissue Marker Migration Study
- Instructions for Use Validation in Cadaver

The EchoMark and EchoMark LP met all specified criteria and did not raise new safety or performance questions and therefore support a finding of substantial equivalence.

Basis for Determination of Substantial Equivalence:
The Indication/Intended Use and the fundamental scientific technology of the EchoMark and EchoMark LP devices have been determined to be substantially equivalent to the predicate device.