



Food and Drug Administration
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Silver Spring, MD 20993-0002

Scion Medical Technologies, LLC
Mr. Louis Li
Quality Assurance/Regulatory Affairs Manager
4613 West Chester Pike
Newtown Square, Pennsylvania 19073

December 17, 2015

Re: K153189
Trade/Device Name: Beacon Tissue Marker (SE)
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: October 3, 2015
Received: November 3, 2015

Dear Mr. Li:

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,

Joshua C. Nipper -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

Indications for Use

510(k) Number (if known)

K153189

Device Name

Beacon Tissue Marker (SE)

Indications for Use (Describe)

Beacon Tissue Marker (SE) is indicated for use to radiographically mark soft tissue at the surgical site during a surgical procedure or for future 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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**Special 510(k) Summary
as required by 21 CFR 807.92(a)**

A) Submitted by: Scion Medical Technologies, LLC

4613 West Chester Pike
Newtown Square, Pennsylvania 19073
USA

Official Contact: Louis Li QA/RA Manager

B) Common name: Implantable Clip

Proprietary Name: Beacon Tissue Marker (SE)

Device Class: Class II, 21 CFR 878.4300
Regulation and
Classification name: marker, radiographic, implantable

Product code: NEU

Classification panel: General and Plastic Surgery

C) Predicate: Beacon Tissue Marker K140835 May 20th, 2014

D) Date Prepared: October 23, 2015

E) Device Description

The Beacon Tissue Marker (SE) consists of a radiographic soft tissue marker and the delivery system. The Beacon Tissue Marker (SE) includes a sterile, single patient use, PEKK discrete marker that is visible on standard radiographs (x-ray, mammography) as well as ultrasound, and Magnetic Resonance Imaging (MRI) at up to 3.0 Tesla field strength.

This submission is for an additional offering of a delivery system with radiused tip and increased rod length corresponding to the new radius tip. The delivery system is sterile, single patient use, and is pre-loaded incorporating the tissue marker. The delivery system has a radius tip 12 cm /14 gauge needle with 1 cm depth marks. The delivery system consists of a cannula with a handle with integral tabs to retain the tissue marker, a push rod with a plunger, and a tip cover. The tissue marker is retained within the delivery system until placement is desired, where it is delivered through the end port by fully depressing the plunger into the handle.

F) Intended Use/Indications For Use:

The Beacon Tissue Marker (SE) is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures

G) Substantial Equivalence Comparison and Discussion

The proposed Beacon Tissue Marker (SE) has the same indications for use and technological characteristics as the predicate device. The proposed and predicate devices have the same:

- intended use
- operational technology
- basic design
- component materials
- sterilization method and sterility assurance level
- packaging materials
- performance characteristics and results

The delivery device cannula tip of proposed Beacon Tissue Marker (SE) is radiused and it is substantially equivalent to the delivery device applicator tip of SenoRx, Inc. StarchMark® Breast Tissue Marker cleared on Jun 27th, 2013 (K131654).

In summary, Scion Medical Technologies, LLC believes that the proposed changes in Beacon Tissue Marker (SE) Delivery Device, as described in this submission, do not raise any new or significant questions of safety and efficacy and is substantially equivalent to the predicate Scion Medical Technologies, LLC Beacon Tissue Marker cleared on May 20th, 2014 (K140835) and SenoRx, Inc. StarchMark® Breast Tissue Marker cleared on Jun 27th, 2013 (K131654)

H) Compliance with Design Controls

The results of assessment of the change to the delivery device, conducted under Design Controls, support that the new offering is substantially equivalent to the predicate device delivery system.

Compliance with Standards:

ISO 15223-1:2012, Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied - Part 1: General requirements

ISO 14971: 2007, Medical devices - Application of risk management to medical devices

EN 1041:2008 Information supplied by the manufacture of medical devices