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

April 27, 2017

Scion Medical Technologies, LLC
Mr. Louis Li
Director of QA/RA
4613 West Chester Pike
Newtown Square, Pennsylvania 19073

Re: K170905
Trade/Device Name: Star Tissue Marker
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: February 28, 2017
Received: March 28, 2017

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" (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 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,

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)*
K170905

Device Name

Star Tissue Marker

Indications for Use *(Describe)*

Star Tissue Marker is indicated for use to radiographically mark soft tissue at the surgical site during a surgical procedure or for future surgical 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

TEL: (484)860-2685

Official Contact: Louis Li Director of QA/RA

B) Common name: Implantable Clip

Proprietary Name: Star Tissue Marker

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: April 26, 2017

E) Device Description

The Star Tissue Marker consists of a radiographic soft tissue marker and the delivery system. The Star Tissue Marker 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 a new cross sectional profile of the tissue marker. The delivery system is sterile, single patient use, and is pre-loaded incorporating the tissue marker. The delivery system has a 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 Star Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures

G) Substantial Equivalence Comparison and Discussion

In summary, Scion Medical Technologies, LLC believes that the proposed changes in Star Tissue Marker, 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).

H) Compliance with Design Controls

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

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