

510(k) Summary

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| Submitter's Name and Address: | Scion Medical Technologies, LLC 90 Oak Street Newton, MA 02464 U.S.A. |
| Contact Name and Information: | Chris Lewis Director QA/RA Scion Medical Technologies, LLC Address: Scion Medical Technologies, LLC 90 Oak Street Newton, MA 02464 U.S.A. Telephone: (617) 209-5629 Fax: (888) 963-9112 E-mail: chris@scionmedtech.com |
| Date Prepared: | 28 March 2014 |
| Proprietary Name(s): | Beacon Tissue Marker™ |
| Common Name: | Implantable Clip |
| Classification Panel | General and Plastic Surgery |
| Classification of Device: | Class II, 21 CFR 878.4300 |
| Product Code: | NEU |
| Predicate Device: | Beacon Tissue Marker K130763 May 8th, 2013 |
| Device Description: | <p>The proposed Beacon Tissue Marker consists of a radiographic soft tissue marker and the delivery system. The proposed Beacon Tissue Marker is 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. The proposed Beacon Tissue Marker is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location.</p> <p>The proposed Beacon Tissue Marker is comprised of Oxford Performance Materials (OPM) OXPEKK-IG200 filled with Barium Sulfate (Polyetherketoneketone with 20% BaSO₄ by wt%). OXPEKK-IG200 is a radiolucent material and serves as the carrier for the radiopaque BaSO₄.</p> <p><u>The proposed Beacon Tissue Marker delivery system is a sterile,</u></p> |

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| | <p>single patient use, pre-loaded delivery system incorporating the Beacon Tissue Marker. The delivery system consists of a cannula with a handle, a push rod with a plunger, tabs to retain the tissue marker, 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. The Beacon Tissue Marker delivery system is used to place the Beacon Tissue Marker into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location. The delivery system device has a beveled 12 cm / 14 gauge needle with 1 cm depth marks and a plunger.</p> |
| Indications for Use: | <p>The Beacon Tissue Marker is indicated for use to radiographically mark soft tissue during a surgical procedure or for future surgical procedures.</p> |
| Technological Characteristics: | <p>The designs of the predicate and proposed Beacon Tissue Markers are the same. Both devices use the same PEKK tissue marker, with the same geometry, and a 20% BaSO₄ loading. The delivery systems are also functionally equivalent. The materials are the same and the plunger/cannula deployment mechanisms are the same. Overall length and system features are equivalent. Both devices employ a retention mechanism to retain the marker in the delivery system. The predicate delivery system uses a vestamid sleeve retention mechanism that is bonded to the ID of the cannula. The proposed device uses two tabs that are precision laser cut into the distal tip of the stainless steel cannula that are bent inward to create a narrowed section in the cannula body to retain the marker.</p> |
| Non-Clinical Testing: | <p>Substantial equivalence of the proposed device was determined through functional, deployment, and package integrity testing. Specifically, testing included deployment force, marker expulsion, component bond strength, marker retention, dimensional, pouch peel, and pouch leak. All testing met pre-defined acceptance criteria.</p> |
| Conclusion: | <p>In summary, Scion Medical Technologies, LLC believes that the proposed Beacon Tissue Marker, as described in this submission, does 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 (K130763) cleared on May 8th, 2013 which is comprised of the Kent Medical Devices, Inc. KMD-Mark1 Tissue Marker (K093473), which was determined to be substantially equivalent and cleared on July 02, 2010, and the Carbon Medical Technologies, Inc. Biomarc Tissue Marker (K063193), which was determined to be substantially equivalent and cleared on November 21, 2006.</p> |



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

May 20, 2014

Scion Medical Technologies Incorporated
Mr. Chris Lewis
Director, Quality Assurance/Regulatory Affairs
90 Oak Street
Newton, Massachusetts 02464

Re: K140835
Trade/Device Name: Beacon Tissue Marker™
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: Class II
Product Code: NEU
Dated: April 23, 2014
Received: April 25, 2014

Dear Mr. Lewis:

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

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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 yours,

David Krause -S

for **Binita S. Ashar, M.D., M.B.A., F.A.C.S.**
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K140835

Device Name
Beacon Tissue Marker™

Indications for Use (Describe)

The Beacon Tissue Marker is indicated for use to radiographically mark soft tissue 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

Peter L. Hudson -S