



Boston Scientific Corporation
% Lindsay Forys
Senior Regulatory Affairs Specialist
100 Boston Scientific Way
MARLBOROUGH MA 01752

December 19, 2017

Re: K173251

Trade/Device Name: LumiCoil Platinum Fiducial Marker
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical Charged-Particle Radiation Therapy System
Regulatory Class: Class II
Product Code: IYE
Dated: October 5, 2017
Received: October 10, 2017

Dear Ms. Lindsay Forys:

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style and is positioned above the printed name and title.

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K173251

Device Name

LumiCoil Platinum Fiducial Marker

Indications for Use (Describe)

The LumiCoil Platinum Fiducial Marker is indicated for use to radiographically mark soft tissue for future therapeutic 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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SECTION 5. 510(K) SUMMARY

510(k) SUMMARY

1. Submitter:

Boston Scientific Corporation
100 Boston Scientific Way
Marlborough, MA 01752

Primary Contact: Lindsay Forys
Senior Regulatory Affairs Specialist
Telephone: 508-683-6317
Fax: 508-683-5939

Secondary Contact: Ashley Santos
Senior Regulatory Affairs Manager
Telephone: 508-683-4359
Fax: 508-683-5939

Date Prepared: 05 October 2017

2. Device:

Trade Name:	LumiCoil™ Platinum Fiducial Marker
Device Common Name:	Soft Tissue Marker
Regulation Name:	Medical charged-particle radiation therapy system
Regulation Number:	21CFR 892.5050
Product Code:	IYE
Regulatory Class:	Class II

3. Predicate Device:

Trade Name:	Visicoil Marker
510(k) Number:	K070305
Device Common Name:	RadioMed Soft Tissue Marker
Regulation Name:	Medical charged-particle radiation therapy system Computed tomography x-ray system
Regulation Number:	21CFR 892.5050 21CFR 892.1750
Product Code:	IYE JAK
Regulatory Class:	Class II

Trade Name:	Visicoil MR Marker
510(k) Number:	K161724
Device Common Name:	Visicoil MR Marker, Pre-Loaded Visicoil MR Marker
Regulation Name:	Medical charged-particle radiation therapy system
Regulation Number:	21CFR 892.5050
Product Code:	IYE
Regulatory Class:	Class II

4. Device Description

The LumiCoil Platinum Fiducial Marker is a helically wound coil made of a platinum alloy wire. The outer diameter of the coil is 0.46mm. The alloy wire is comprised of ~92% platinum and ~8% tungsten. The LumiCoil Marker is available in two shape configurations: straight and figure 8. The length of the fiducial markers when implanted is 5mm.

The LumiCoil Marker is recommended to be placed using the 22ga Expect Slimline (SL) Endoscopic Ultrasound Aspiration Needle.

5. Indications for Use:

The LumiCoil Platinum Fiducial Marker is indicated for use to radiographically mark soft tissue for future therapeutic procedures.

6. Technological Characteristics

The intended use of the proposed LumiCoil Marker is identical to the predicate Visicoil Marker (K070305) and Visicoil MR Marker (K161724). The fiducial markers are comprised of helically wound wire and can be implanted using an endoscopic ultrasound (EUS) needle. In addition, both the LumiCoil Marker and the Visicoil MR Marker (K161724) are primarily made of platinum.

7. Performance Data

Non-clinical performance bench testing and simulated use testing were completed to evaluate the design of the LumiCoil Marker for its indications for use.

Comparative testing was performed to demonstrate the visibility of the LumiCoil Marker and the predicate Visicoil Marker.

Conclusion

The information provided in this submission demonstrates that the proposed LumiCoil Marker is substantially equivalent to the Visicoil Marker (K070305) and the Visicoil MR Marker (K161724).