



Food and Drug Administration
10903 New Hampshire Avenue
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July 27, 2015

Anchor Innovation Medical
c/o Karen M. Becker, Ph.D.
5410 Edson Lane, Suite 308
Rockville, MD 20852

Re: K150924

Trade/Device Name: A.I.M. Lead Loop Suturing Device
Regulation Number: 21 CFR 882.5880
Regulation Name: Stimulator, Spinal Cord, Implanted (Pain Relief)
Regulatory Class: Class II
Product Code: GZB and GAT
Dated: April 30, 2015
Received: May 1, 2015

Dear Dr. Becker:

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,

Carlos L. Pena - 

Carlos L. Peña, Ph.D., M.S.

Director

Division of Neurological and Physical
Medicine Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150924

Device Name

A.I.M. Lead Loop Suturing Device

Indications for Use (Describe)

The A.I.M. Lead Loop Suturing Device is intended for use in securing Spinal Cord Stimulation (SCS) leads and catheters to the fascia or intra-spinous/supra-spinous ligament.

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.

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2.0 510(K) SUMMARY: A.I.M. LEAD LOOP SUTURING DEVICE

Submission Date: July 23, 2015

Submitter Information:

Company: Anchor Innovation Medical (A.I.M.)
5410 Edson Lane
Suite 308
Rockville, MD 20852

Contact Person: Cary Stalnecker
Chief Executive Officer

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Device Information:

Trade Name: A.I.M. Lead Loop Suturing Device

Regulation Name: Stimulator, Spinal Cord, Implanted (Pain Relief)

Classification: 21 CFR 882.5880

Product Codes: GZB/GAT

Device Class: Class II

Predicate Devices: Boston Scientific Fixate Suturing Device (K113805)

Intended Use: The A.I.M. Lead Loop Suturing Device is intended for use in securing Spinal Cord Stimulation (SCS) leads and catheters to the fascia or intra-spinous/supra-spinous ligament.

Device Description: The A.I.M. Lead Loop Suturing Device is a singular anchor threaded with an adjustable loop of non-absorbable size 0 suture. The suture material is commercially available Ultra-High Molecular Weight Polyethylene or Polyester braid. The anchor is composed of carbon fiber reinforced polyetheretherketone (PEEK OPTIMA®) supplied by Invibio®. The device is provided sterile and pre-loaded in a needle-tipped, disposable-delivery device to facilitate insertion into tissue. A sterile, disposable ancillary instrument is available separately, or included with the Lead Loop Suturing Device, to assist with tensioning the construct and trimming the suture once the appropriate tension is achieved.

Substantial Equivalence Summary:

The A.I.M. Lead Loop Suturing Device is substantially equivalent to the cited predicate, Boston Scientific's Fixate Suturing Device, having the same, or similar, intended use, indications for use, and fundamental scientific technology.

The A.I.M. Lead Loop Suturing Device and predicate differ in suture anchor count, the means of tensioning and capturing the SCS lead anchor or catheter, and retaining tension.

Comparative performance testing with the predicate demonstrated equivalent performance and did not raise any new questions of safety or effectiveness.

Performance Testing: Bench testing was conducted to confirm that the A.I.M. Lead Loop Suturing Device performs as well or better than the predicate in cyclic loading and ultimate device/construct failure.

Safety Testing: The A.I.M. Lead Loop Suturing Device was determined to be biocompatible based on conformity with ISO 10993. Component materials and assembly processes are identical or similar to those utilized within the A.I.M. Knotless Meniscal Repair Device (K133770) and Suture Anchor (K132461).

Conclusion: Based on the similarity in intended use, materials, fundamental scientific technology and performance testing, the A.I.M. Lead Loop Suturing Device is substantially equivalent to the cited predicate.