



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Innova Spinal Technologies, LLC
% Rich Jansen, Pharm.D.
President
Silver Pine Consulting, LLC
11821 Bramble Cove Drive
Fort Myers, Florida 33905

May 7, 2015

Re: K150954

Trade/Device Name: ELITE™ L Expandable Lumbar Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 7, 2015
Received: April 9, 2015

Dear Dr. Jansen:

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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K150954

Device Name

ELITE™ L Expandable Lumbar Fusion System

Indications for Use (Describe)

The ELITE™ L Expandable Lumbar Fusion System is indicated for use as intervertebral body fusion devices in skeletally mature patients with Degenerative Disc Disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine from L2-L5. Patients should have received a minimum of six months of non-operative treatment prior to surgery. These patients may also have up to grade I spondylolisthesis or retrolisthesis at the involved level(s). These implants are intended for use with autogenous bone graft and supplemental internal fixation systems such as a pedicle screw or anterior plating system.

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

510(k) SUMMARY

Elite L Expandable Lumbar Fusion System

Date: April 7, 2015
Submitter: Armando Varela
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Telephone: 561-504-5431

Regulatory Contact: Rich Jansen, Pharm. D.
Silver Pine Consulting, LLC
612-281-5505

Product

Trade Name: Elite™ L Expandable Lumbar Fusion System
Common Name: Intervertebral Body Fusion Device
Product Class: Class II
Classification: 21 CFR 888.3080
Product Code: MAX
Panel Code: 87

Purpose:

The purpose of this submission is to add devices to be implanted from the lateral surgical approach.

Device Description

The Elite™ L is a titanium alloy (Ti6Al4V-ELI) implant that is designed to provide mechanical support of the intradiscal space while biologic fusion occurs. The device is available in a variety of footprints, all of which are inserted in the unexpanded state and are expanded in situ. There are various heights to accommodate varied patients' anatomy. The implants are available in parallel and lordotic angles, with the implant end plates being bi-convex to optimize contact with the vertebral body end plates. All implants are made from medical grade titanium alloy. Implants have a locking mechanism to hold the implant in the expanded position once deployed.

Predicate Device

The predicate devices include the Primary Predicate which is the Elite IBF by Innova Spine (K133459). Additional predicates include the Clydesdale Spinal System from Medtronic (K100175) and the Coroent XL Keeled System by Nuvasive (K081611).

Intended Use / Indications for Use

The ELITE™ L Expandable Lumbar Fusion System is indicated for use as intervertebral body fusion devices in skeletally mature patients with Degenerative Disc Disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) at one or two contiguous levels of the lumbar spine from L2-L5. Patients should have received a minimum of six months of non-operative treatment prior to surgery. These patients may also have up to grade I spondylolisthesis or retrolisthesis at the involved level(s). These implants are intended for use with autogenous bone graft and supplemental internal fixation systems such as a pedicle screw or anterior plating system.

Performance Testing

The Primary Predicate Device, the Elite Expandable Interbody Fusion Device was tested according to ASTM F2077 and ASTM F2267. Testing included static and dynamic axial compression, subsidence and expulsion. The Elite™ L device was compared to the Primary Predicate using FEA and demonstrated greater strength and durability to static and dynamic forces compared to the Primary Predicate. A complete analysis is provided.

Performance Characteristics:

The Elite™ L is substantially equivalent to the predicate devices in regards to:

- Indications for Use
- Materials
- Dimensions
- Function
- Mechanical testing

Summary:

The Elite™ L demonstrates substantial equivalence to the predicate devices and raises no new questions of safety and effectiveness.