

510(k) Summary

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Company Name: SeaSpine, Inc.
An Integra Life Sciences Company
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Vista, CA 92081

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Date Prepared: August 23, 2013

Trade Name: Integra Spinous Process System
Common Name: Spinous Process System
Classification Name: Spinal Interlaminar Fixation Orthosis
Classification: 21 CFR 888.3050, Class II
Product Codes: PEK

Device Description: The Integra Spinous Process System consists of an implantable spacer featuring plates of varying lengths with fixed hub diameters and set screws in order to clamp bilaterally to the spinous processes. It is a multicomponent device consisting of two plates coupled by a central hub and locked by a set screw. Each plate contains spikes for fixation to the spinous process to aid in resisting rotation after implantation. The device is available in a range of sizes to accommodate variations in patient pathology and anatomy. It is manufactured from Ti-6Al-4V ELI per ASTM F136. The device is provided non-sterile and is single use only. The complete system, including insertion and accessory instrumentation for implantation, is packaged in a tray for transportation, cleaning and sterilization.

Intended Use: Integra Spinous Process System is a posterior non-pedicle supplemental fixation system intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/ attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions:

- degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- spondylolisthesis
- trauma (i.e., fracture or dislocation)
- spinal tumor

The device is not intended for stand-alone use.

Predicate Devices: Integra Spinous Process System is substantially equivalent, in whole or in part, to the following commercially available predicate devices in design, materials, indications and performance:

Life Spine Interspinous Fixation System K100407
NuVasive® Spinous Process Plate System K073278

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Lanx Spinous Process Fusion Plate (SPFP) K090252; K083581; K043484
Medtronic CD Horizon Spinous Process Plate K032037

- Technological Characteristics:** The technological characteristics of the Integra Spinous Process device are the same as the referenced devices in that it is composed of two clamping plates, a locking set screw, various hub diameters and Ti-6AL-4V per ASTM F136.
- Testing Summary:** Performance testing and a detailed engineering analysis were provided to demonstrate substantial equivalence with respect to compression bending and torsion. Test standards referenced were ASTM F1717 and ASTM F1798. Analysis and interpretation of the test results and device comparisons demonstrate that the Integra device is substantially equivalent to the predicate devices.
- Conclusions:** The information submitted in this premarket notification supports a determination that the Integra Spinous Process System is substantially equivalent in technological characteristics and intended use to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 04, 2013

SeaSpine, Incorporated
Mr. Nicholas M. Cordaro
Director of Engineering
2302 La Mirada Drive
Vista, California 92081

Re: K121924
Trade/Device Name: Integra Spinous Process System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminar fixation orthosis
Regulatory Class: Class II
Product Code: PEK
Dated: August 27, 2013
Received: August 28, 2013

Dear Mr. Cordaro:

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 Small Manufacturers, International and Consumer Assistance 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 CDRI'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 Small Manufacturers, International and Consumer Assistance 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): K121924

Device Name: Integra Spinous Process System

Indications for Use:

Integra Spinous Process System is a posterior non-pedicle supplemental fixation system intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions:

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- spinal tumor

The device is not intended for stand-alone use.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ronald P. Jean -S

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K121924.