510(k) Summary

MAY 01 2014

1. Contact Details

Applicant Name: SeaSpine, Inc.
(A subsidiary of Integra LifeSciences Corporation)

Address: 2302 La Mirada Drive, Vista, CA 92081
Phone number: (760) 727-8399
Fax number: (760) 727-8809

Contact person: Jeff Brittan – Director, Engineering
Email address: jeff.brittan@integralife.com

Date Prepared: March 28, 2014

2. Device Name

Trade Name: Integra® Expandable Intervertebral Body Fusion Device (IBD) System

Common Name: Interbody Fusion Device

Classification Name: Intervertebral Body Fusion Device (21 CFR 888.3080)
Product Code: MAX, Class II, Orthopedic Review Panel

3. Legally Marketed Predicate Devices

510(k) Number	Product Code	Trade Name	Manufacturer
K082310	MAX	SeaSpine Spacer System – Pacifica™	SeaSpine
K071724	MAX	Lucent™ Intervertebral Body Fusion Device	Spinal Elements
K102293, K123231	MAX	Caliber™ Spacers	Globus Medical

4. Device Description

The Integra Expandable IBD System consists of lumbar interbody fusion devices manufactured from PEEK-OPTIMA® LT1 (ASTM F2026), titanium (Ti-6Al-4V ELI per ASTM F136) and cobalt chromium (Co-28Cr-6Mo per ASTM F1537) materials, with radiographic tantalum markers (ASTM F560). These implants are generally box shaped with surface teeth and a central channel to be filled with autogenous bone graft. They are available in a range of sizes, and their heights can be intra-operatively expanded to the desired height to accommodate variations in surgical approach and patient anatomy. Non-expandable implants are manufactured from PEEK-OPTIMA® LT1 only with radiopaque markers. The system also includes instruments to assist with the surgical procedure/ implantation, as well as trays and caddies for organization.

5. Intended Use/Indications for use

The Integra Expandable Interverterbal Body Fusion Device (IBD) System is intended for spinal fusion procedures at one or two contiguous levels (L2-S1) in skeletally mature patients with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s). These patients should have had six months of non-operative treatment. The device is intended to be used with autogenous bone graft and supplemental fixation.

6. Substantial Equivalence Comparison

The Integra Expandable IBD System is substantially equivalent to the cited predicate devices in areas including intended use/indications for use, technological characteristics (operating principle, design, materials, sterility, manufacturing, etc.) and performance (mechanical safety).

7. Non-clinical Testing

The Integra Expandable IBD System demonstrated equivalent performance to the predicate systems through static and dynamic axial compression and compression shear testing per ASTM F2077, with wear evaluation per ASTM F1877, subsidence testing per ASTM F2267, and expulsion testing per ASTM Draft F04.25.0202. In addition, a cadaver implantation study was conducted to demonstrate usability and graft containment/volume of the subject device.

8. Clinical Testing

No clinical testing was required to demonstrate equivalence.

9. Conclusions

The submitted data demonstrate that the Integra Expandable IBD System is substantially equivalent to the cited legally marketed predicate devices.

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

May 1, 2014

SeaSpine, Incorporated
Mr. Jeffrey Brittan
Director, Engineering
2302 La Mirada Drive
Vista, California 92081

Re: K133418
Trade/Device Name: Integra® Expandable Intervertebral Body Fusion Device (IBD) System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: April 2, 2014
Received: April 3, 2014

Dear Mr. Brittan:

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,

Ronald P. Jean -S for

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

Enclosure

Indications for Use Statement

510(k) Number: K133418

Device Name: Integra® Expandable Interverterbal Body Fusion Device (IBD) System

Indications for Use:

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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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices