MAY - 1 2012

510(k) Summary

Manufacturer:
Integra Spine, LLC
1153 Medina Road
Medina, OH 44256
Phone: 330 239 7700
Fax: 330 239 4216

Contact:
Dale Davison
Vice President of Engineering
Integra Spine, LLC
1153 Medina Road
Medina, OH 44256
Office.: 330-239-7709
Fax: 330-239-4216
Email: dale.davison@integralife.com

Date Prepared: April 18, 2012

Device Trade Name: Integra Vu aPOD-L Intervertebral Body Fusion Device

Classification: §888.3080, Intervertebral body fusion device

Class: II

Product Code: OVD, MAX

Predicate Device: Theken Spine Vu aPOD Intervertebral Body Fusion Device (K080822)

Device Description:

The Integra Vu aPOD-L Intervertebral Body Fusion Device consists of spinal fusion cages, optional internal buttress plates, as well as instrumentation designed specifically for the implantation of these devices. The spinal fusion cages are offered in heights of 8-16mm, lengths of 44-64mm, widths of 18mm and 23mm, and lordotic angled geometries to accommodate variations in patient anatomy. The cages include teeth on the top and bottom surfaces to engage with the superior and inferior end plates of neighboring vertebral bodies to resist rotation and migration. The cages contain an open central channel for receiving bone graft to allow for bony in-growth in and around the implant. The cages can be used in combination with an optional titanium spin plate and contain radiographic markers. The devices are manufactured from Polyetheretherketone (PEEK-OPTIMA LT-1) per ASTM F2026, Titanium alloy (Ti-6Al-4V ELI) per ASTM F136, and Tantalum per ASTM F560.

Indications For Use:
The Integra Vu aPOD-L Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The device is to be packed with autogenous bone graft (i.e. autograft). The Integra Vu aPOD-L Intervertebral Body Fusion Device is intended for use with supplemental fixation that is in addition to the integrated buttress spin plate, such as a pedicle screw system or anterior plate.

Degenerative disc disease is defined as back pain of discogenic origin, with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment.

Substantial Equivalence Comparison:
The technological characteristics of the Integra Vu aPOD-L Intervertebral Body Fusion Device are the same as the predicate device Theken Spine Vu aPOD Intervertebral Body Fusion Device (K080822).

The subject device similarities include:

- The same indications for use
- The same basic design
- The same materials
- Used in conjunction with supplemental fixation
- The same sterilization process
- The same packaging configurations

Performance Standards:
Mechanical testing was performed per ASTM F2077 (static axial compression, static compress-shear, dynamic axial compression), ASTM F2267 (static subsidence) and expulsion as part of standard design control activity, demonstrating that the Integra Vu aPOD-L Intervertebral Body Fusion Device is substantially equivalent to the predicate device.

Clinical Testing:
There was no clinical or animal testing performed for this submission.

Conclusion:
Integra Spine believes that sufficient information has been presented to demonstrate that the Integra Vu aPOD-L Intervertebral Body Fusion Device is substantially equivalent to the predicate device with respect to safety, efficacy and performance, and has the same indications, intended use, and technological features to the legally marketed device listed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Integra Spine, LLC
% Mr. Dale Davison
Vice President of Engineering
1153 Medina Road
Medina, Ohio 44256

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Re: K112986
Trade/Device Name: Integra Vu aPOD-L Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVD, MAX
Dated: April 18, 2012
Received: April 20, 2012

Dear Mr. Davison:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Statement of Indications For Use

510(k) Number (if known): _K112986_

Indications For Use:

The Integra Vu aPOD-L Intervertebral Body Fusion Device is indicated for use as an adjunct to fusion in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may also have up to Grade 1 spondylolisthesis at the involved level(s). The device is to be packed with autogenous bone graft (i.e. autograft). The Integra Vu aPOD-L Intervertebral Body Fusion Device is intended for use with supplemental fixation that is in addition to the integrated buttress spin plate, such as a pedicle screw system or anterior plate.

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Prescription Use ___√___ (Part 29 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (29 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)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112986