K110045

3. 510(k) SUMMARY

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510(k) SUMMARY

[as required by section 807.92(c)]

510(k) Owner's Name:	Vertebral Technologies, Inc.
Address:	5909 Baker Road, Suite 550 Minnetonka, MN 55345
Phone/Fax/Email:	Office: (952) 979-9357 Company Main Tel: (952) 912-5400 Fax: (952) 912-5410 Email: sghai@vti-spine.com
Name of Contact Person:	Suresh Ghai VP, Quality & Regulatory Affairs
Date prepared:	10 December 2010
Trade or Proprietary Name:	InterFuse® DA Intervertebral Body Fusion Device
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Fusion Device with Bone Graft, Lumbar 21 CFR § 888.3080 Product code: MAX Device Class: II

3.1 Legally Marketed Device to Which Your Firm is Claiming Equivalence

The modified device (InterFuse® DA Intervertebral Body Fusion Device) is substantially equivalent in performance, indication, design and material to VTI's own InterFuse® P Intervertebral Body Fusion Device cleared under Premarket notification # K091988.

3.2 DEVICE DESCRIPTION

The implantable portion of VTI's InterFuse DA interbody fusion device (IFD) is made of implantable grade PEEK (Poly ether ether ketone), a polymer with a history of use in interbody fusion device designs, and which has a compressive modulus similar to bone. Each segment of the device has embedded tantalum beads that aid in visualizing the implanted device under x-ray and to aid in position retention when assembled in the disc space. Each segment has an integral rail and / or slot which slide through or over the rail or slot in the adjacent segment to complete the device (see photos below). Each segment incorporates a stop to help ensure that it is properly aligned with the adjacent segment. The exposed rail, with a stainless steel (Grade 304) tail, of each segment is removed after the adjacent segment is installed. The modular system allows for as few as three segments to be used, although most patients will require between four and six segments for optimum coverage of the vertebral endplate. Each segment has a vertical slot through the device for the surgeon to fill with autogenous bone that will provide a path for solid bone growth during the fusion process. The device is produced in four heights and two anterior-posterior dimensions to fit a range of potential disc spaces. The device will also be produced in flat and angled (lordotic) shapes to fit the angular geometry of the disc at each disc level.

3.3 INTENDED USE OF THE DEVICE

[The Intended Use and Indications for the modified device, as described in its labeling are the same as the Intended Use and Indications for the unmodified 510(k) cleared device (K091988].

The InterFuse® DA Intervertebral Body Fusion Device is indicated for intervertebral spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The InterFuse DA device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The InterFuse DA device is indicated for use with autogenous bone graft and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine.

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3.4 TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE

The modified device (InterFuse® DA Intervertebral Body Fusion Device) is substantially equivalent in performance, indication, design and materials to InterFuse® P Intervertebral Body Fusion Device from our company (VTI), cleared under premarket notification # K091988. The implanted portion of both devices is exactly same in performance, indication, materials and design except that in case of devices with lordotic profile the lordosis (5°) is on the anterior end of each segment in the modified device.

The implantable portion of the modified device and the unmodified device (K091988) uses the same raw material (PEEK-OPTIMA and Tantalum beads) and has the same geometric design. Same (molded) segment blanks are machined to get finished segments of the modified device and the predicate device (K091988).

The packaging material, packaging configuration, sealing parameters (& the sealing equipment), method of sterilization and stertility assurance level (SAL) has remained unchanged in the modified device from that of the unmodified device.
The modified device will be implanted by an ALIF (anterior lumbar Interbody fusion) technique compared with the predicate device (K091988) which is implanted by a PLIF [(unilateral) posterior lumbar Interbody fusion)] technique.

3.5 SUMMARY AND CONCLUSIONS FROM THE NONCLINICAL TESTS SUBMITTED

The substantial equivalence is supported by comparing the material of construction, manufacturing process, packaging and sterilization processes of the modified device and the un-modified (predicate) device (K091988).

The basic design of the implantable portion of the device has not changed from the 510(k) cleared device (K091988). There is no difference in the parallel profile devices for the modified device and the predicate device. The design changes of the modified device are limited to the lordosis of the segments in the devices with lordotic profile. The performance of the modified devices was tested for static compression in accordance with ASTM F2077-

03 – *Test methods for Intervertebral Body Fusion Devices* to confirm that this change did not have an impact on the device.
The assembled devices were compressed axially from 0 lb_f to failure using displacement control at 25 mm/min at ambient conditions. Load vs. displacement were plotted and peak load was computed. All devices exceeded the minimum strength requirement of 8,500N which was used in the original validation testing referenced in K091988. The static compression testing was done per ASTM 2077-03 – *Test Methods for Intervertebral Body Fusion Devices* (Report TR 582 is attached in Appendix 1).

On the basis of performance data it is concluded that the modified device is substantially equivalent to the unmodified device (K091988).

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

FEB - 3 2011

Vertebral Technologies, Inc.
% Suresh Ghai
Vice President, Quality and Regulatory Affairs
5909 Baker Road, Suite 550
Minnetonka, Minnesota 55345

Re: K110045
Trade/Device Name: InterFuse® Intervertebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: December 10, 2010
Received: January 06, 2011

Dear Suresh Ghai:

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.

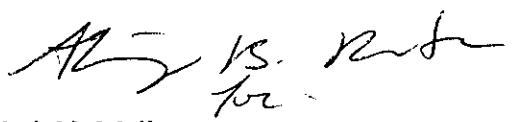
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

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

Enclosure

2. STATEMENT OF INDICATION FOR USE

Indication for Use

510(k) Number (if known): K110045

Device Name: InterFuse® Intervertebral Body Fusion Device

Indications for Use:

The InterFuse® DA Intervertebral Body Fusion Device is indicated for intervertebral spinal fusion procedures in skeletally mature patients with degenerative disc disease (DDD) at one or two contiguous levels from L2-S1. DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies. These patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). The InterFuse DA device is to be used in patients who have had at least six (6) months of non-operative treatment. These patients may have had a previous non-fusion surgery at the involved spinal level(s). The InterFuse DA device is indicated for use with autogenous bone graft, and to be used with supplemental internal spinal fixation systems that have been cleared for use by the FDA in the lumbosacral spine.

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)

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

510(k) Number K110045

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