K091988

JUL 30 2009

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 Director, Regulatory Affairs
Date prepared:	30 JUNE, 2009
Trade or Proprietary Name:	InterFuse® 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

LEGALLY MARKETED DEVICE TO WHICH YOUR FIRM IS CLAIMING EQUIVALENCE

The modified InterFuse® Intervertebral Body Fusion Device is substantially equivalent in performance, indication, design and material to VTI's own InterFuse® Intervertebral Body Fusion Device cleared under Premarket notification # K 080673.

DEVICE DESCRIPTION

The implantable portion of VTI's IFD device is made of PEEK (Poly ether ether ketone), a polymer with a history of use in interbody fusion devices, 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. Each segment incorporates a stop to help ensure that it is properly aligned with the adjacent segment. The exposed rail, with a stainless steel 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

K091988

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 (8, 10, 12 and 14 mm) and two anterior-posterior dimensions (20 mm and 25 mm) to fit a range of potential disc spaces. The device will also be produced in flat and 5°angled (lordotic) shapes to fit the angular geometry of the disc at each disc level.

INTENDED USE OF THE DEVICE

The InterFuse® 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 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 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.

TECHNOLOGICAL CHARACTERISTICS COMPARED TO PREDICATE DEVICE

The modified InterFuse® Intervertebral Body Fusion Device is substantially equivalent in performance, indication, design and materials to InterFuse® Intervertebral Body Fusion Device from our company (VTI), cleared under premarket notification # K080673. The implanted portion of both devices is exactly same in performance, indication, design and materials.

The design changes to the InterFuse device are limited to the configuration of the device tail, which is part of device segment delivery system and is not implanted into the patient.

The only other change to the device is use of a gamma irradiation sterilization process vs. the EtO sterilization of the un-modified device (K080673).

SUMMARY AND CONCLUSIONS FROM THE NONCLINICAL TESTS SUBMITTED

The substantial equivalence is supported by bench testing comparing the modified InterFuse® Intervertebral Body Fusion Device to the predicate device (K080673). The design changes of the modified device are limited to the configuration of the tail, which is part of the delivery system for the segments of the device. The tails are not implanted. The other change to the device is method of sterilization by gamma irradiation. The performance of the irradiated devices was tested for static compression in accordance with ASTM F2077-03 – *Test methods for Intervertebral Body Fusion Devices* to confirm that the gamma sterilization process did not have an impact on the device material. All devices exceeded the minimum strength requirement which was used in the original validation testing referenced in K080673.
The sterilization by gamma irradiation was validated to give a Sterility Assurance Level of 10^{-6}.

The InterFuse device was found to be "Non toxic" by testing for cytotoxicity.

On the basis of performance data it is concluded that the modified device is substantially equivalent to the unmodified device (K080673).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vertebral Technologies Inc.
% Mr. Suresh Ghai
Director, Regulatory Affairs
5909 Baker Road, Suite 550
Minnetonka, Minnesota 55345

JUL 30 2009

Re: K091988
Trade/Device Name: InterFuse® Intervetebral Body Fusion Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: II
Product Code: MAX
Dated: June 30, 2009
Received: July 2, 2009

Dear Mr. 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.

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 (240) 276-3150 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

Indication for Use

510(k) Number (if known): K091988

Device Name: InterFuse® Intervertebral Body Fusion Device

Indications for Use:

The InterFuse® 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 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 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 K091988