## Section 8 - 510(k) Summary

FEB 0 7 2013

| | |
|---|---|
| **Date:** | 21 December 2012 |
| **Sponsor:** | DiFusion Technologies<br>111 Cooperative Way<br>Georgetown, TX 78626<br>Phone: 512-863-7777<br>Facsimile: 512-628-3084 |
| **Contact Person:** | Jami Hafiz, Ph.D., Vice-President Development |
| **Trade Names:** | XIPHOS™ ALIF |
| **Device Classification** | Class II |
| **Classification Name:** | Spinal vertebral body replacement device; Intervertebral fusion device with bone graft, lumbar |
| **Regulation:** | 888.3060; 888.3080 |
| **Device Product Code:** | MQP; MAX |
| **Device Description:** | The XIPHOS™ ALIF is a lumbar PEEK interbody fusion device. These implants can be described as an oval structural column having a central strut. The superior and inferior surfaces are open with parallel serrations. The implants are available in an assortment of height, depth, width and anteroposterior angulation combinations to accommodate a variety of anatomic requirements. |
| **Intended Use:** | When used as an intervertebral body fusion device, the DiFUSION Technologies XIPHOS Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.<br><br>When used as a vertebral body replacement device, the DiFUSION Technologies XIPHOS System is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The XIPHOS System is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. These devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The DiFUSION Technologies XIPHOS System is intended to be used with autograft or allograft bone. |
| **Materials:** | The XIPHOS™ ALIF is manufactured from polyetheretherketone (PEEK) per ASTM F2026 (VESTAKEEP® i4 R, Evonik Polymers Technologies GmbH). Integral marker pins are manufactured from tantalum according to ASTM F560. |

| | |
|---|---|
| **Predicate Devices:** | DiFusion Technologies (K100042)<br>Eminent Spine LLC (K090064)<br>Theken Spine (K080822) |
| **Performance Data:** | Mechanical testing of the worst case XIPHOS™ ALIF was performed according to ASTM F2077 and included static and dynamic compression and static and dynamic torsion. The subsidence properties were evaluated according to ASTM F2267.<br>The mechanical test results demonstrate that the XIPHOS™ ALIF device performance is substantially equivalent to the predicate devices. |
| **Technological Characteristics:** | The XIPHOS™ ALIF device possesses the same technological characteristics as the predicate devices. These include:<br>• performance (as described above),<br>• basic design (hollow structural frame),<br>• material (PEEK polymer and tantalum), and<br>• sizes (widths, lengths and heights are within the range(s) offered by the predicate).<br>Therefore the fundamental scientific technology of the XIPHOS™ ALIF device is the same as previously cleared devices. |
| **Conclusion:** | The XIPHOS™ ALIF devices possess the same intended use and technological characteristics as the predicate devices. Therefore the XIPHOS™ ALIF is substantially equivalent for its intended use. |

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

Difusion Technologies
% Backroads Consulting, Inc.
Karen E. Warden, PhD
PO BOX 566
Chesterland, Ohio 44026

Letter dated: February 7, 2013

Re: K123969
Trade/Device Name: XIPHOS™ ALIF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX, MQP
Dated: December 21, 2012
Received: December 26, 2012

Dear Dr. Warden:

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

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

Enclosure

## Section 7 - Indications for Use Statement

510(k) Number: K123969

Device Name: **XIPHOS™ ALIF**

Indications for Use:

When used as an intervertebral body fusion device, the DiFUSION Technologies XIPHOS Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to SI, in skeletally mature patients who have had six months of non-operative treatment. The device is intended for use at either one level or two contiguous levels for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The device system is designed for use with supplemental fixation and with autograft to facilitate fusion.

When used as a vertebral body replacement device, the DiFUSION Technologies XIPHOS System is indicated for use to replace a vertebral body that has been resected or excised (i.e. partial or total vertebrectomy) due to tumor or trauma/fracture. The XIPHOS System is intended for use in the thoracolumbar spine (from T1 to L5) and is intended for use with supplemental fixation. These devices are designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column even in the absence of fusion for a prolonged period. The DiFUSION Technologies XIPHOS System is intended to be used with autograft or allograft bone.

Prescription Use __X__ OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

---

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Stephanie Bechtold -S
2013.02.07 14:00:37 -05'00'

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K123969