November 1, 2019

DiFusion Technologies
% John J. Smith, M.D., J.D.
Partner
Hogan Lovells
555 Thirteenth Street NW
Washington, District of Columbia 20004

Re: K190544
Trade/Device Name: XIPHOS™ ZFUZE™ Interbody Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: October 28, 2019
Received: October 28, 2019

Dear Dr. Smith:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Ronald P. Jean, Ph.D.
Director (Acting)
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below

510(k) Number *(if known)*

K190544

Device Name

XIPHOS™ ZFUZE™ Interbody Fusion System

Indications for Use *(Describe)*

The XIPHOS™ ZFUZE™ Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, 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 is designed for use with supplemental fixation and with autograft to facilitate fusion.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) SUMMARY

DIFUSION TECHNOLOGIES XIPHOS™ ZFUZE™ INTERBODY FUSION SYSTEM

Submitter:

DiFusion Technologies
1624 Headway Circle
Austin, Texas- 78754
Phone: 512-284-3338
Contact Person: Derrick W. Johns

Date Prepared:

October 30, 2019

Name of Device:

XIPHOS™ ZFUZE™ Interbody Fusion System

Common or Usual Name:

Intervertebral body fusion device

Classification Name:

Intervertebral Body Fusion Device, 21 CFR 888.3080

Regulatory Class:

Class II

Product Code:

MAX

Primary Predicate Device:

XIPHOS™ Interbody Fusion System (K100042): The XIPHOS™ Interbody Fusion System is a Class II device regulated under 21 CFR 888.3080.

DEVICE DESCRIPTION

The XIPHOS™ ZFUZE™ Interbody Fusion System is a single use sterile- packed permanent implant identical to that of the construct in the cleared XIPHOS™ Interbody Fusion system (K100042). The DiFUSION Technologies XIPHOS™ ZFUZE™ Interbody Fusion System is comprised of various sizes and configurations to accommodate individual patient anatomy. The configurations are designed to provide the surgeon with different surgical approach options. The XIPHOS™ ZFUZE™ Interbody Fusion System will be offered in two (2) configurations of various sizes like its predicate

XIPHOS™. The configurations are designed based on indicated spinal implant level and surgical approach, and consist of: 1) XIPHOS™ ZFUZE™ PLIF, posterior lumbar approach and 2) XIPHOS™ ZFUZE™ TLIF, transforaminal lumbar approach.

XIPHOS™ ZFUZE™ Interbody Fusion System implants consist of bullet shaped (PLIF) and banana shaped (TLIF) blocks in a parallel configuration of various heights. Large bone graft windows are located through the body of the device to allow for placement of bone graft to facilitate fusion. The superior and inferior surfaces of the devices have a pattern of teeth to provide increased stability and inhibit movement of the implants.

Additionally, the device contains four (4) radiolucent tantalum markers in the PLIF configuration and five (5) radiolucent tantalum markers in TLIF configuration to assist the surgeon with proper placement of the device. The PLIF device may be implanted singularly or in pairs via a posterior approach while The TLIF device may be implanted singularly via a transforaminal approach.

The XIPHOS™ ZFUZE™ Interbody Fusion System is made of Ketaspire PEEK (KT1211FP) and Type 4A Zeolite. In addition tantalum beads are embedded in the spacers to allow radiographic visualization. These permanent implants are available for prescription use only.

INDICATIONS FOR USE

The XIPHOS™ ZFUZE™ Interbody Fusion System is indicated for intervertebral body fusion of the lumbar spine, from L2 to S1, 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 is designed for use with supplemental fixation and with autograft to facilitate fusion.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Intervertebral body fusion through Posterior or Transforminal approach is the technological principle for both the subject and predicate device. Appropriate surgical instrumentation is used to insert the implants into the intervertebral space in order to assist in fusion. At a high level the subject and predicate XIPHOS™ Interbody fusion devices are based on the following common technological elements:

- Implant Design – PLIF & TLIF
- Indications for Use
- Intended Use
- Surgical Technique

The technological difference that exists between the subject (XIPHOS™ ZFUZE™) and predicate device is in the material composition. XIPHOS™ ZFUZE™ Interbody device is composed of PEEK and Type 4A Zeolite while the predicate XIPHOS™ implants contains PEEK exclusively. This difference in material composition does not raise a concern as it is shown to be substantially equivalent to the predicate.

PERFORMANCE DATA

The XIPHOS™ ZFUZE™ Interbody Fusion System was tested in compliance with FDA's guidance document titled "Class II special controls Guidance Document: Intervertebral Body Fusion Device" and demonstrated substantially equivalent performance characteristics to XIPHOS™ (K100042) implants which is the predicate device.

Mechanical Testing on the final device that has been gamma irradiated and aged include:

- Static Compression (ASTM F2077)
- Dynamic Compression (ASTM F2077)
- Static Torsion (ASTM F2077)
- Dynamic Torsion (ASTM F2077)
- Wear Debris (ASTM F1877)
- Expulsion
- Subsidence (ASTM F2267)

Biocompatibility assessment for the XIPHOS™ ZFUZE™ Interbody Fusion System was conducted in accordance with the FDA Blue Book Memorandum #G95-1 and the most recent FDA-recognized International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process". The battery of testing also included in vitro and in vivo material assessment.

CONCLUSIONS

The overall intended use and indication, technological characteristics and performance data conclude that the XIPHOS™ ZFUZE™ Interbody Fusion System is shown to be substantially equivalent to the predicate XIPHOS™ Interbody Fusion System (K100042).