510(K) SUMMARY

MAY 19 2010

1. GENERAL INFORMATION

Date Submitted	December 18, 2008
Trade Name	IMPIX-ALIF LUMBAR Interbody Device (Model IMPIX-LA) IMPIX-ALIF D LUMBAR Interbody Device (Model IMPIX-LAD) IMPIX-TLIF LUMBAR Interbody Device (Model IMPIX-TLIF)
Common Name	intervertebral body fusion device
Classification Name	intervertebral body fusion device – lumbar
Class	II
Product Code	MAX
CFR section	888.3080
Device panel	Orthopedic
Legally marketed predicate devices	IMPIX Lumbar Interbody Device, MAX (K072226)
Submitter	MEDICREA Technologies Z.I. Chef de Baie 17000 La Rochelle, France
Contact	Donald W. GUTHNER 111 Hill Road Douglasville, PA 19518

2. PREDICATE DEVICE DESCRIPTION

The IMPIX Lumbar Cage is bi-convex in the sagittal plane. It possesses teeth on both superior and inferior surfaces that assist in the anchorage and stability of the device to the bone of the vertebrae. The upper and lower aspects of the IMPIX-L are open, to allow the surgeon to pack the device with bone graft prior to insertion. Lateral holes exist to allow bone growth through the device. In order to adapt to the varying morphology of patients, the IMPIX Lumbar Cages are available in various sizes. The IMPIX Lumbar Cage is machined from PEEK OPTIMA LT1.

3. DESCRIPTION OF DEVICE MODIFICATION

The purpose of this submission is to submit three new Lumbar Interbody devices:

- IMPIX-LA
- IMPIX-LAD
- IMPIX-TLIF

Those three new devices and previously cleared in K072226 IMPIX-L Interbody devices are manufactured in the same material, PEEK OPTIMA® LT1, and have the same Indications for use. The devices differ only in design.

4. INTENDED USE

IMPIX Lumbar Interbody Device is indicated for intervertebral body 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 DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft.

IMPIX Lumbar Interbody Device is to be used with supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

5. PERFORMANCE DATA

Tests performed, according to ASTM F2077 & ASTM F2267, indicate that the IMPIX Lumbar Interbody Fusion devices meet required mechanical strengths. Tests conducted included axial compression, compressive shear, resistance to subsidence and resistance to expulsion.

In addition, a cadaver trial was performed to demonstrate implantation technique.

6. CLINICAL TESTING

Not applicable to this device

7. CONCLUSIONS

Based on the 510(k) Summary and the information provided herein, we conclude that the IMPIX LUMBAR Interbody Fusion Devices are substantially equivalent to the existing legally marketed device under the Federal Food, Drug and Cosmetic Act.

8. Additional Information

No additional information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY 19 2010

Medicrea Technologies
% Donald W. Guthner
Orgenix, LLC
111 Hill Road
Douglassville, PA 19518

Re: K083798
Trade/Device Name: Impix ALIF Lumbar IBF, ALIF-D Lumbar IBF, TLIF Lumbar IBF
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 12, 2010
Received: May 13, 2010

Dear Mr. Guthner:

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.

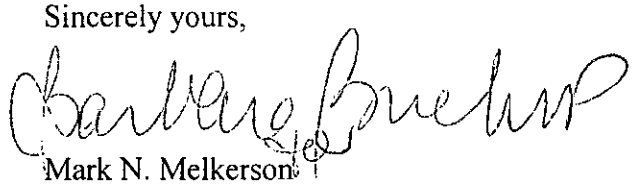
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

INDICATIONS FOR USE

510(k) Number (if known):

Device Name: IMPIX Lumbar Interbody Devices

Indications for Use

IMPIX Lumbar Interbody Device is indicated for intervertebral body 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 DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). This device is to be used with autogenous bone graft.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

510(k) Number K083798