MEDICREA

510(k) Summary for the IMPIX DLIF

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the IMPIX DLIF.

Date Prepared: June 14, 2010

1. **Submitter:**

MEDICREA TECHNOLOGIES
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Contact Person:

J.D. Webb
The OrthoMedix Group, Inc.
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Telephone: 512-388-0199

2. **Trade name:** IMPIX DLIF LUMBAR Interbody Device
   Common Name: Intervetebral body fusion
   Classification Name: Intervertebral body fusion device - lumbar

3. **Predicate or legally marketed devices which are substantially equivalent:**
   - The IMPIX-L Lumbar Cages (MEDICREA, K072226)
   - The ORACLE Spacer (Synthes, K072797)
   - The CROSS-FUSE (Pioneer, K073177)
   - The Vu-a-Pod (Theken spine, K080822)

4. **Description of the device:**

   The purpose of this submission is to submit the new Lumbar Interbody device: IMPIX-DLIF. The DLIF, or Dual Lateral Interbody Fusion, has a rectangular shape with a front beveled and has three areas inside for use with autogenous bone graft.

   This new device and IMPIX-L Interbody devices previously cleared in K072226 are manufactured in the same material, PEEK OPTIMA® LT1, and have the same Indications for use. The devices differ in geometry and approach.

   Materials: PEEK OPTIMA LT1

   Function: The IMPIX DLIF was developed as an implant:
   - to maintain and/or to restore the intervertebral height and the spinal curve (after discectomy)
   - to promote bone fusion
   - to provide stability to ease fusion
   - to be mechanically resistant to allow the fusion of the operated level

5. **Substantial equivalence claimed to predicate devices**

   IMPIX DLIF is substantially equivalent to the IMPIX-L in terms of intended use, materials used, mechanical safety and performances, and the ORACLE Spacer or the Cross-Fuse in terms of intended use, design, materials used, mechanical safety and performances. IMPIX DLIF 40mm is substantially equivalent to the Vu-a-Pod for an antero-lateral approach.

   The table below compares the features and characteristics of the IMPIX DLIF to these predicate devices.

Device	IMPIX DLIF	IMPIX-L Interbody Device (MEDICREA)	ORACLE Spacer (SYNTHES)	Vu-a-Pod (Theken Spine)	CROSS-FUSE (Pioneer)
510(k) number	/	K072226	K072791	K080822	K073177
Intended use					

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Device	IMPIX DLIF	IMPIX-L Interbody Device (MEDICREA)	ORACLE Spacer (SYNTHES)	Vu-a-Pod (Theken Spine)	CROSS-FUSE (Pioneer)
Lumbar spine	Yes	Yes,	Yes	Yes	Yes
Anterolateral Approach	Yes, only with the 40mm DLIF cages	No	No	Yes	No
Lateral Approach	Yes	No	Yes	No	Yes
Design					
Bone graft cavity	Yes	Yes	Yes	Yes	Yes
Teeth / ridges	Yes	Yes	Yes	Yes	Yes
X-Ray Markers	Yes	Yes	Yes	Yes	Yes
Shape	Rectangular shape	Rectangular shape	Oval shape	Rectangular shape	Rectangular shape
Materials					
Lumbar cage	PEEK OPTIMA® LT1 (ASTM F2026)	PEEK OPTIMA® LT1 (ASTM F2026)	PEEK OPTIMA® LT1 (ASTM F2026)	PEEK OPTIMA LT1 (ASTM F2026)	PEEK OPTIMA® LT1 (ASTM F2026)
Pins markers	Tantalum (ISO 13782)	Tantalum (ISO 13782)	Tantalum (ISO 13782)	Titanium, Ti-6Al-4V ELI (ASTM F-136)	Tantalum (ISO 13782)

6. **Intended Use:**

IMPIX DLIF 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 DLIF 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.

7. **Non-clinical Test Summary:**

Testing was performed on the IMPIX DLIF following the protocols outlined in ASTM F2077 "Test Methods for Intervertebral Body Fusion Devices" and ASTM F2267 "Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression".

The following tests were conducted:

- Static axial Compression results
- Static compression-shear results
- Static torsion results
- Static subsidence results

8. **Clinical Test Summary**

No clinical studies were performed

9. **Conclusions Nonclinical and Clinical**

IMPIX DLIF is substantially equivalent to the predicate devices in terms of indications for use, design, material and function.

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

Medicrea Technologies
% The OrthoMedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

JUL 22 2010

Re: K100544
Trade/Device Name: IMPIX® DLIF Lumbar Interbody Device
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: June 18, 2010
Received: June 22, 2010

Dear Mr. Webb:

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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): ___K100544_____
Device Name: IMPIX® DLIF
Indications for Use:

IMPIX DLIF 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 DLIF 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.

Prescription Use ✓ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K100544