K121323

JUL 18 2012

510(k) Summary for the MEDICREA® INTERNATIONAL anterior lumbo-sacral plate

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the lumbo-sacral plate.

Date Prepared: 25/04/2012

1. **Submitter:**

MEDICREA INTERNATIONAL
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NEYRON 01700
FR

Contact Person:

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14 Porte du Grand Lyon
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2. **Trade name:** Anterior Lumbo-Sacral Plate

   Common Name: Lumbar Stabilization Device

   Classification Name: Spinal intervertebral body fixation orthosis

   Classification and Regulation: KWQ-888.3060- Appliance, Fixation, Spinal Intervertebral Body.

3. **Predicate or legally marketed devices which are substantially equivalent:**
   - The Alphatec Spine Anterior Lumbar Plating System, (Alphatec Spine, K101255)
   - The Spinal USA Anterior Lumbar Plate System (Spinal USA, K091044)
   - The Pyramid® +4 Anterior Lumbar Plate System (MEDTRONIC, K080429)

4. **Description of the device:**

The MEDICREA® Anterior Lumbo sacral Plate system is a stabilization device for use as an adjunct to fusion. The implant is composed of :

- one lumbo sacral plate
- either 3 or 4 anterior lumbar screws , depending on the lumbosacral plate considered in the range

The anterior lumbar screw is manufactured from titanium alloy meeting ASTM F136 and ISO 5832-3 standards, and the lumbosacral plate is manufactured from titanium alloy meeting ASTM F136 and ISO 5832-3 and PEEK OPTIMA® meeting the ASTM F 2026.

Materials: Titanium alloy and PEEK OPTIMA® LT1
Function: The Anterior Lumbosacral Plate was developed as an implant:

- to supplement an interbody device with an anterior fixation
- provide anterior stabilization to the lumbar spine
- to augment the development of a solid spinal fusion
- to provide stability to ease fusion
- to be mechanically resistant to allow the fusion of the operated level

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5. Intended Use

MEDICREA® INTERNATIONAL anterior lumbo-sacral plate system is designed to be used at L5/S1 level. It is intended for use as anteriorly placed supplemental fixation device via the anterior surgical approach below the great vessel bifurcation. The device is intended as a temporary fixation device until fusion is achieved.

MEDICREA® INTERNATIONAL anterior lumbo-sacral plate system is intended for anterior lumbar spine at L5/S1 level, for the following indications:

1. Degenerative Disc Disease (DDD) at L5/S1 level. (DDD is defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies)
2. Pseudoarthrosis
3. Spondylolysis
4. Trauma (i.e., fracture or dislocation)
5. Spinal stenosis
6. Deformities and or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
7. Tumor
8. Failed previous fusion.

MEDICREA® INTERNATIONAL anterior lumbo-sacral plate is intended to be used with autograft and or allograft as an adjunct to fusion.

Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage and a lumbo-sacral plate for degenerative conditions.

6. Substantial equivalence claimed to predicate devices

MEDICREA® INTERNATIONAL Anterior Lumbosacral Plate is substantially equivalent to the Alphatec Spine Anterior Lumbar Plating System and Spinal USA anterior plate system, in terms of intended use, materials used, mechanical safety and performances, and the Pyramid in terms of intended use, design, materials used.

- The Alphatec Spine Anterior Lumbar Plating System, (Alphatec Spine, K101255)
- The Spinal USA Anterior Lumbar Plate System (Spinal USA, K091044)
- The Pyramid® +4 Anterior Lumbar Plate System (MEDTRONIC, K080429)

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The table below compares the features and characteristics of MEDICREA® INTERNATIONAL Anterior Lumbosacral Plate to these predicate devices.

Device	STABOLT Lumbo sacral plate	ASPIDA (Alphatec Spine)	Lumbar Plate (Spinal USA)	Pyramid +4 Anterior lumbar plate (Medtronic)
510(k) number		K101255	K091044	K080429
Intended use				
Lumbar spine (L5/S1)	Yes	Yes	Yes	Yes
Anterior Approach below the great vessel bifurcation	Yes	Yes	Yes	Yes
Design				
Anchorage mean	3 or 4 screws	4 screws	4 screws	3 or 4 screws
Security features	Screws clipped within the PEEK OPTIMA® LT1 insert	Screws clipped within the titanium plate	Rotating anti-back out system	A cover plate
Shape	Triangular shape	Rectangular shape	Rectangular shape	Triangular shape
Materials				
Stabilization device	Ti-6Al-4V (ASTM F136 & ISO 5832-3)	Ti-6Al-4V (ASTM F136 & ISO 5832-3)	Ti-6Al-4V (ASTM F136 & ISO 5832-3)	Ti-6Al-4V (ASTM F136 & ISO 5832-3)
Security features	PEEK OPTIMA® LT1 (ASTM F2026)	Ti-6Al-4V (ASTM F136 & ISO 5832-3)	Ti-6Al-4V (ASTM F136 & ISO 5832-3)	Ti-6Al-4V (ASTM F136 & ISO 5832-3)

Material composition is identical to other MEDICREA® INTERNATIONAL products that have been cleared via the 510(k) process.

7. Non-clinical Test Summary:

Testing was performed on the MEDICREA® Anterior Lumbosacral Plate system following the protocols outlined in ASTM F1717 "*Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model*".

The following tests were conducted:

- Static axial Compression
- Static torsion
- Dynamic compression

8. Clinical Test Summary

No clinical studies were performed

9. Conclusions Nonclinical and Clinical

MEDICREA® Anterior Lumbosacral Plate system is substantially equivalent to its 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 International
% Ms. Laure Aviron-Violet
Regulatory Affairs Manager
14 Porte du Grand Lyon
Neyron France 01700

JUL 18 2012

Re: K121323
Trade/Device Name: Anterior Lumbo-Sacral Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 27, 2012
Received: May 02, 2012

Dear Ms. Aviron-Violet:

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,

Erin Keith

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

Enclosure

K121323

Statement of Indications for Use

510(k) Number (if known): _____

Device Name:

Lumbo-Sacral Plate

Indications for Use:

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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 K121323

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