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

December 8, 2016

Medicrea International S.A.
David Ryan
VP Product Development and Marketing
14 Porte Du Grand Lyon
Neyron, 01700 France

Re: K162194
Trade/Device Name: MEDICREA INTERNATIONAL Anterior Cervical Locking Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 10, 2016
Received: November 14, 2016

Dear Mr. Ryan:

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 contact the Division of Industry and Consumer Education 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. 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 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 Industry and Consumer Education 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,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K162194

Device Name
MEDICREA INTERNATIONAL Anterior Cervical Locking Plate System

Indications for Use *(Describe)*
MEDICREA INTERNATIONAL S.A. Anterior Cervical Locking Plate System is intended for anterior interbody screw/ plate fixation of the cervical spine until the bone fusion occurs.
The MEDICREA INTERNATIONAL S.A. Anterior Cervical Locking Plate System is indicated for use in the temporary stabilization of the anterior cervical (C2 to T1) spine during development of a solid fusion in patients with the following conditions:
• degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
• spondylolisthesis,
• trauma (i.e., fracture or dislocation),
• spinal stenosis,
• deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
• tumor,
• pseudoarthrosis,
• and failed previous fusion
This implant has to be used with an appropriate bone graft.
Patients should have been unresponsive for a minimum six (6) weeks to conservative treatment before the surgery.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

MEDICREA INTERNATIONAL Anterior Cervical Locking Plate System

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for MEDICREA INTERNATIONAL Anterior Cervical Locking Plate System:

Date Prepared: 02 August 2016

1. **Submitter:**

MEDICREA INTERNATIONAL
14 Porte du Grand Lyon
NEYRON 01700
FR
Phone Number : +33 4 72 01 87 87

Contact Person:

David RYAN
MEDICREA INTERNATIONAL
14 Porte du Grand Lyon
NEYRON 01700
FR

2. **Trade name:** MEDICREA INTERNATIONAL Anterior Cervical Locking Plate System

Regulatory Identification/ Classification

SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS
Regulation Number: 21CFR 888.3060
Product Code: KWQ
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**

Primary predicate:

- MaxAn Anterior Cervical Plate System, (BIOMET SPINE, K133518)

Additional predicate:

- Stella Cervical Plate, (SCIENT'X, K052763)
- Synthes Spine Anterior CSLP System (SYNTHES SPINE, K030866)
- Uniplate Anterior Cervical Plate System (DEPUY SPINE, K100070)

No reference devices were used in this submission.

4. **Description of the device:**

MEDICREA INTERNATIONAL Anterior Cervical Locking Plate System is an anterior system, which consists of a variety of cervical plate lengths and a variety of cervical bone screws.

The implants are manufactured in titanium alloy Ti-6Al-4V ELI conforming to ISO 5832-3 specifications and ASTM F136 specifications.

Never use stainless steel and titanium implant components in the same construct.

To achieve best results, do not use any of the MEDICREA INTERNATIONAL Anterior Cervical Locking Plate System components with components from any other systems or manufacturer unless specifically labeled to do so in this or another MEDICREA® INTERNATIONAL document.

MATERIALS: Titanium Alloy (Ti-6Al-4V) according to the ASTM F136-11 & ISO 5832-3

Function: MEDICREA INTERNATIONAL Anterior Cervical Locking Plate System was developed as an implant:

- To provide immobilization and stabilization of anterior spinal segments
- 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

5. Indication for Use

MEDICREA INTERNATIONAL S.A. Anterior Cervical Locking Plate System is intended for anterior interbody screw/plate fixation of the cervical spine until the bone fusion occurs.

The MEDICREA INTERNATIONAL S.A. Anterior Cervical Locking Plate System is indicated for use in the temporary stabilization of the anterior cervical (C2 to T1) spine during development of a solid fusion in patients with the following conditions:

- degenerative disc disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies),
- spondylolisthesis,
- trauma (i.e., fracture or dislocation),
- spinal stenosis,
- deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
- tumor,
- pseudoarthrosis,
- and failed previous fusion

This implant has to be used with an appropriate bone graft.

Patients should have been unresponsive for a minimum six (6) weeks to conservative treatment before the surgery.

6. Substantial equivalence claimed to predicate devices

MEDICREA INTERNATIONAL S.A. Anterior Cervical Locking Plate components are technologically similar to the already cleared Stella Cervical Plate; MaxAn Anterior Cervical Plate System, Synthes Spine Anterior CSLP System, and Uniplate Anterior Cervical Plate System from Depuy Spine components in terms of intended use, materials used, mechanical safety and performances.

The table below compares the features and characteristics of MEDICRA INTERNATIONAL Anterior Cervical Locking Plate components to their predicate devices.

Device	MEDICREA INTERNATIONAL Anterior Cervical Locking Plate System	BIOMET SPINE MaxAn Anterior Cervical Plate System	SYNTHES SPINE Anterior CSLP System	DEPUY SPINE Uniplate Anterior Cervical Plate	SCIENT'X STELLA Cervical Plate
510(k) number	Unknown	K133518	K030866	K100070	K132012
Intended use					
Anterior Cervical	Yes	Yes	Yes	Yes	Yes
Components					
Cervical Plate	1-Level Plate 2-Level Plate 3-Level Plate 4-Level Plate	1-Level Plate 2-Level Plate 3-Level Plate 4-Level Plate 5-Level Plate	1-Level Plate 2-Level Plate 3-Level Plate 4-Level Plate	1-Level Plate 2-Level Plate	1-Level Plate 2-Level Plate 3-Level Plate 4-Level Plate 5-Level Plate
Cervical Screws	Ø4mm & Ø4.5mm Variable and fixed angles screws available	Ø4mm & Ø4.5mm Variable and fixed angles screws available	Ø4mm & Ø4.35mm & Ø4.5mm Variable and fixed angles screws available	Ø4,6mm & Ø5.2mm	Ø4mm & Ø4.5mm Variable and fixed angles screws available
Locking Mechanism					
	Part turned to prevent screw back out	Based on titanium elasticity, ring deformation	Based on Titanium deformation, a locking screw is screwed within the screw head	Part turned to prevent screw back out	Part turned to prevent screw back out
Materials					
	Titanium Alloy (Ti-6Al-4V) according to ASTM F136 & ISO 5832-3	Titanium Alloy (Ti-6Al-4V) according to ASTM F136 & ISO 5832-3	Titanium Alloy (Ti-6Al-4V) according to ASTM F136 & ISO 5832-3	Titanium Alloy (Ti-6Al-4V) according to ASTM F136 & ISO 5832-3	Titanium Alloy (Ti-6Al-4V) according to ASTM F136 & ISO 5832-3

7. Non-clinical Test Summary:

The components of MEDICREA INTERNATIONAL Anterior Cervical Locking Plate System were mechanically evaluated in static and dynamic compression and static torsion tests following the ASTM F1717-15.

Pyrogenicity testing was conducted in support to MEDICREA INTERNATIONAL Anterior Cervical Locking Plate System component substantial equivalence.

8. Clinical Test Summary

No clinical data was provided

9. Conclusions Non clinical and Clinical

MEDICREA INTERNATIONAL Anterior Cervical Locking Plate System is substantially equivalent to legally marketed predicate device.