JUL 2 4 2014

510(k) SUMMARY

Medicrea's C-JAWS Compressive Cervical Staple

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

Date Prepared: July 23, 2014

Submitter:

MEDICREA INTERNATIONAL
14 Porte du Grand Lyon
NEYRON 01700
FRANCE

Contact Person:

Audrey VION
Regulatory Affairs Manager
MEDICREA INTERNATIONAL

Trade Name:

C-JAWS Cervical Compressive Staple

Common Name:

Anterior Cervical Stabilization Device

Classification Name:

Anterior staple as supplemental fixation for fusion

Product Code and Regulation:

PHQ, 21 C.F.R. 888.3060

Predicate Devices

Depuy Spine Uniplate Anterior Cervical Plate System (K042544)

Synthes Orozco Plate (K792352)

Intended Use / Indications for Use

The C-JAWS cervical compressive staple is intended for anterior cervical intervertebral body fixation. This system is indicated for patients as part of an anterior cervical fusion procedure for the indications listed below. The intended levels for treatment range from C3 to C7.

Indications are limited to patients with degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), at one level, with radiculopathy and/or myelopathy with herniated disc producing symptomatic nerve root and or spinal compression confirmed by radiographic studies and/or with

osteophyte formation on the posterior vertebral endplates producing symptomatic nerve root and or spinal compression confirmed by radiographic studies.

The C-JAWS cervical compressive staple is limited to one level fusion. A single C-JAWS staple must be implanted per functional segment unit fused. It MUST be used with a cervical interbody fusion device filled with autograft.

WARNING: The C-JAWS cervical compressive staple is not intended for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Technological Characteristics

The C-JAWS cervical compressive staple device is a single component system. The device is shaped to conform to the anatomy of the anterior spine. It features two ridged extension legs, which engage the vertebral bodies and allow secure anchorage of the device and anti-back-out using a locking mechanism.

Materials: The C-JAWS cervical compressive staple device is manufactured from CP Titanium (T40, ASTM F-67). The complete C-JAWS cervical compressive staple device contains Class I instruments and non-implantable devices manufactured from stainless steel.

Non-clinical Test Summary

Mechanical testing indicates that the C-JAWS cervical compressive staple device is capable of performing in accordance with its intended use. Testing was performed on the C-JAWS following the protocols outlined in ASTM F1717 "Standard Test Methods for Spinal Implant Constructs in a Vertebrectomy Model".

The following tests were conducted:

- □Static Compression
- □Static torsion
- □Dynamic compression

Clinical Test Summary

The clinical safety and performance of the C-JAWS was established by clinical studies that involved 118 patients who underwent cervical fusion with the C-JAWS, an interbody fusion device, and autograft. Data from these studies demonstrate an overall fusion rate of 95.8% and a safety profile directly comparable to standard of care fusion using allograft and anterior cervical plate.

Substantial Equivalence

Based on the clinical performance data, the C-JAWS compressive staple has been shown to be as safe and effective, as compared to the predicate devices when used per the cleared indications. The C-JAWS has similar materials, technological characteristics and principles

of operation as its predicate devices. Thus, the C-JAWS cervical compressive staple is substantially equivalent to the referenced predicate devices.

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

July 24, 2014

Medicrea International, Incorporated
% John J. Smith, M.D., J.D.
Hogan Lovells US LLP
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

Re: K133906
Trade/Device Name: C-JAWS Cervical Compressive Staple
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: PHQ
Dated: June 24, 2014
Received: June 24, 2014

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. 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 yours,

Ronald P. Jean -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)*
K133906

Device Name
C-JAWS Cervical Compressive Staple

Indications for Use *(Describe)*
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Indications are limited to patients with degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies), at one level, with radiculopathy and/or myelopathy with herniated disc producing symptomatic nerve root and/or spinal compression confirmed by radiographic studies and/or with osteophyte formation on the posterior vertebral endplates producing symptomatic nerve root and or spinal compression confirmed by radiographic studies.

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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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Katherine D. Kavlock, PhD

Division of Orthopedic Devices

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