September 3, 2021

Medicrea International S. A.
Karine Trogneux
Regulatory Affairs Department Manager
5389 route de Strasbourg - Vancia
Rillieux-La-Pape, 69140
France

Re: K210470
Trade/Device Name: C-CURVE
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE, ODP
Dated: July 23, 2021
Received: August 4, 2021

Dear Karine Trogneux:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Brent L. Showalter, Ph.D.
Assistant Director
DHT6B: Division of Spinal Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210470

Device Name
C-CURVE

Indications for Use *(Describe)*
The C-CURVE® Device is an anterior cervical intervertebral body fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) (defined as pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) at one disc level from C2 to T1. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The device is indicated to be used with autograft bone and/or allograft bone comprised of cancellous and/or corticocancellous bone and/or demineralized allograft bone with bone marrow aspirate. The device is a stand-alone system when used C-Curve screws and when used without the integrated screws it requires additional supplemental fixation cleared for the cervical spine.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY

The Company's 510(k) Summary is provided on the following pages.

510(k) SUMMARY
MEDICREA INTERNATIONAL's C-Curve

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

Date Prepared: February, 15, 2021
Prepared answers: July, 23, 2021

1. **Submitter:**

MEDICREA INTERNATIONAL
5389 route de Strasbourg – Vancia
RILLIEUX-LA-PAPE 69140
FR

Contact Person:

Karine Trogneux
MEDICREA INTERNATIONAL
5389 route de Strasbourg - Vancia
RILLIEUX-LA-PAPE 69140
FR

2. **Trade name:** C-Curve

Regulatory Identification/ Classification

Intervertebral Fusion Device With Integrated Fixation, Cervical / Intervertebral Fusion Device With Bone Graft, Cervical
Regulation Number: 21CFR 888.3080
Product Code: OVE, ODP
Class II

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

Primary predicate device:

- Endoskeleton TCS Interbody Fusion Device (Titan Spine, K192018)

Additional predicate devices:

- HIJAK SA (Atlas Spine, K192570)
- PEEK Prevail (Medtronic, K073285, K153373)
- Optio-C (ZIMMER SPINE, K132894)

None of those devices have not been subject to a design-related recall.

4. Description of the device:

MEDICREA® INTERNATIONAL S.A. C-CURVE® is composed of a cervical cage range stabilized by C-CURVE® screws. The titanium cage is composed of two pre-assembled components (the cage body and an expansion screw) that enable its expansion and adaptation of its lordotic angle. The cages are delivered individually and the screws are provided separately by two. The cages are available in different footprints and heights. These implants are designed to be inserted between two adjacent cervical vertebrae after removal of the disc. C-CURVE® is implanted by anterior approach. It is important to refer to the surgical technique and to the Instructions For Use (see paragraph «IMPLANT INSERTION», especially to use the two
screws to stabilize the cage). C-CURVE® can be considered as a stand-alone cage if the two screws are used to stabilize the cage. If it is not the case, an additional fixation system must be added. Titanium cages & screws are manufactured in titanium alloy Ti-6Al-4V ELI conforming to ISO 5832-3 specifications and ASTM F136 specifications. Under no circumstances are the implants reusable.

MATERIALS: Components are manufactured from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136 and ISO 5832-3.

Function:

C-Curve was developed as an implant:
- To restore and maintain adequate interbody height.
- To stabilize the spine at one level & promote bony fusion.

5. Indication for Use

C-CURVE® is an anterior cervical intervertebral body fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) (defined as pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) at one disc level from C2 to T1. Patients should have received 6 weeks of non-operative treatment prior to treatment with the device. The device is indicated to be used with autograft bone and/or allograft bone comprised of cancellous and/or corticocancellous bone and/or demineralized allograft bone with bone marrow aspirate. The device is a stand-alone system when used C-Curve screws and when used without the integrated screws it requires additional supplemental fixation cleared for the cervical spine.

6. Substantial equivalence claimed to predicate devices

The C-Curve components are technologically similar to the already cleared predicates: the Titan Spine Endoskeleton TCS (K192018), the Atlas Spine HiJak SA (K192570), the Medtronic PEEK Prevail (K073285, K153373) and the ZIMMER SPINE Optio-C (K132894) in terms of intended use, material used, mechanical safety and performances.

The table below compares the features and characteristics of the submitted C-Curve components to their predicate devices.

Device	***MEDICREA INTERNATIONAL C-Curve***	**TITAN SPINE Endoskeleton TCS**	**ATLAS SPINE HiJAK SA**	**Medtronic PEEK Prevail**	**ZIMMER SPINE Optio-C**
510(k) number	To be determined	K192018	K192570	K073285, K153373	K132894
Intended use					
Cervical via anterior approach	Yes	Yes	Yes	Yes	Yes
Components					
Device components	Cage & 2 screws	Cage & 2 screws	Cage/plate & 2 screws	Cage & 2 screws	Cage/plate & 3 screws
Material					
	Cage: Ti-6Al-4V ELI Screws: Ti-6Al-4V ELI	Cage: Ti-6Al-4V ELI Screws: Ti-6Al-4V ELI	Cage: Ti-6Al-4V ELI Screws: Ti-6Al-4V ELI	Cage: PEEK, Tantalum & Nitinol Screws: Ti-6Al-4V ELI	Cage: PEEK, Ti-6Al-4V ELI Screws: Ti-6Al-4V ELI
Sterile state					
	Provided sterile	Provided sterile	Provided non sterile	Provided sterile	Provided sterile

7. Non-clinical Test Summary:

The following performance data was provided in support of the substantial equivalence determination.

Biocompatibility Testing

The C-Curve components are made from the same materials as its predicates and the manufacturing processes are similar to the ones of the predicates.

Mechanical testing

The tests performed on the C-Curve components (Static & Dynamix Axial Compression, Static & Dynamic Torsion, Static and Dynamic Compression Shear per ASTM F2077 , Subsidence per ASTM F2267 and Postero-anterior expulsion) indicate that the product is mechanically equivalent to its predicates.

8. Conclusions

The subject C-Curve device demonstrated equivalent mechanical performance to the cited predicate device under the same test conditions.

The overall technology characteristics and mechanical performance data lead to the conclusion that the subject device is substantially equivalent to legally marketed predicate devices.