May 4, 2018

Precifit Medical Ltd
% Kellen Hills
Quality and Regulatory Consultant
Orchid Design
4600 E Shelby Drive
Memphis, Tennessee 38118

Re: K172568
Trade/Device Name: Cervage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: ODP
Dated: April 5, 2018
Received: April 9, 2018

Dear Kellen Hills:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172568

Device Name
Cervage

Indications for Use *(Describe)*
The Cervage cage is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2-C3 disc to the C7-T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks on non-operative treatment. The Cervage cage is to be used with supplemental fixation. The Cervage cage is also required to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and is to be implanted via an open, anterior approach.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

[As Required by 21 CFR 807.92]

(a)(1)	Submitted By:	PRECIFIT MEDICAL LTD
	Address:	2233 5th Street East, St Paul, MN, 55119
	Phone:	901-433-1990
	Date:	April 5, 2018
	Contact Persons	
	Primary:	Kellen Hills (Orchid Design Consulting)
	Secondary:	Eric Wu (Precifit Medical Ltd)
(a)(2)	Proprietary Name:	Cervage
	Common Name:	Cervical interbody fusion device, interbody cage
	Classification Name and Reference:	21 CFR 888.3080: Intervertebral Fusion Device With Bone Graft, Cervical
	Product Code:	ODP
(a)(3)	Predicate Devices:	
	Primary:	Medtronic® ANATOMIC PEEK PTC CERVICAL FUSION SYSTEM (K133653);
	Additional:	Medtronic® ANATOMIC PEEK CERVICAL FUSION SYSTEM (K112444)
	Reference:	Precifit Medical LUMFUSE-TP (K171630)

(a)(4) Device Description:

The Cervage cage consists of PEEK cages of various lengths and heights, which can be inserted between two cervical vertebral bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The devices are made from PEEK radiolucent material (ASTM F2026) with embedded tantalum x-ray markers (ASTM F560 or ISO 13782). The coated cages are coated with medical grade CP Ti (ASTM F1580) and are provided sterile. The non-coated cages are provided sterile or non-sterile. The device must be used with supplemental fixation.
The purpose of this submission is to gain initial marketing authorization in the United States.

(a)(5) Indications for Use:

The Cervage cage is indicated for cervical interbody fusion procedures in skeletally mature patients with cervical disc disease at one level from the C2 - C3 disc to the C7 - T1 disc. Cervical disc disease is defined as intractable radiculopathy and/or myelopathy with herniated disc and/or osteophyte formation on posterior vertebral endplates producing symptomatic nerve root and/or spinal cord compression confirmed by radiographic studies. This device is to be used in patients who have had six weeks of non-operative treatment. The Cervage cage is to be used with supplemental fixation. The Cervage cage is also required to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft and is to be implanted via an open, anterior approach.

(a)(6) Comparison of Technological Characteristics:
The Cervage device has the same intended use and is similar in basic shape, material and performance characteristics to the predicate device. The technological characteristics do not raise any new questions of safety and efficacy.

(b)(1) Non-clinical testing:
The worst case devices were evaluated for mechanical performance in Static and Dynamic Axial Compression, Static and Dynamic Torsion, Static and Dynamic Compression Shear according to ASTM F2077-14, Subsidence according to ASTM F2267-04 and Expulsion in accordance with ASTM F-04.25.02.02. Cleaning and sterilization as well as implantable device biocompatibility endpoints were also evaluated.

(b)(2) Clinical testing:
Clinical testing was not required to demonstrate substantial equivalence in this premarket notification.

(b)(3) Conclusions:
Based on the information provided in this premarket notification, we believe that the subject Cervage device demonstrates substantial equivalence to the identified predicate devices.