June 8, 2018

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

Re: K173189
Trade/Device Name: Lumfuse TP
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: May 8, 2018
Received: May 11, 2018

Dear Mr. 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 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,

Katherine D. Kavlock -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173189

Device Name
Lumfuse-TP

Indications for Use *(Describe)*
The Lumfuse-TP cage is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. When used for these indications, the Lumfuse-TP cage is intended for use with supplemental fixation systems cleared for use in the lumbar spine. These patients should be skeletally mature and have had six months of nonoperative treatment. The Lumfuse-TP cage is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion.

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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"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:	May 8, 2018
	Contact Persons	
	Primary:	Kellen Hills (Orchid Design Consulting)
	Secondary:	Eric Wu (Precifit Medical Ltd)
(a)(2)	Proprietary Name:	Lumfuse-TP
	Common Name:	Lumbar interbody fusion device, interbody cage
	Classification Name and Reference:	21 CFR 888.3080: Intervertebral Fusion Device, Lumbar
	Product Code:	MAX
(a)(3)	Predicate Devices:	
	Primary:	Precifit LUMFUSE-TP (K171630)
	Additional:	Medtronic® CAPSTONE PTC (K133205);
	Additional:	Precifit CERVAGE (K172568);

(a)(4) Device Description:

The Lumfuse-TP cage consists of PEEK cages of various lengths and heights, which can be inserted between two lumbar or lumbosacral vertebral bodies to give support and correction during lumbar 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). Two versions of the Lumfuse-TP cage are available: cages coated with medical grade CP Ti (ASTM F1580) and non-coated cages, both of which are provided sterile. The device must be used with supplemental fixation.

The purpose of this submission is to gain initial marketing authorization in the United States for the non-coated, sterile and TPS coated Lumfuse-TP devices. Associated instrumentation has already been cleared in K171630.

(a)(5) Indications for Use:

The Lumfuse-TP cage is intended to be used in spinal fusion procedures for patients diagnosed with Degenerative Disc Disease (DDD) at one or two contiguous levels from L2 to S1. DDD patients may also have up to Grade 1 Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. When used for these indications, the Lumfuse-TP cage is intended for use with supplemental fixation systems cleared for use in the lumbar spine. These patients should be skeletally mature and have had six months of nonoperative treatment. The Lumfuse-TP cage is intended to be used with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft when the subject device is used as an adjunct to fusion.

(a)(6) Comparison of Technological Characteristics:

The Lumfuse-TP has the same intended use and is similar in basic shape, material and performance characteristics to the predicate device. The technological characteristics demonstrate substantial equivalence to the identified predicate devices.

(b)(1) Non-clinical testing:
The worst case devices were evaluated for mechanical performance in Static and Dynamic Axial Compression and Static and Dynamic Compression Shear according to ASTM F2077-14, and Subsidence according to ASTM F2267-04(2011). Cleaning and sterilization processes as well as implantable device biocompatibility endpoints were 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 Lumfuse-TP demonstrates substantial equivalence to the identified predicate devices.