DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 8, 2017

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

Re: K163327
Trade/Device Name: Precifit Medical Kirschner Wires
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HTY, JDW
Dated: April 25, 2017
Received: April 28, 2017

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.

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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163327

Device Name
Precifit Medical Kirschner Wires

Indications for Use *(Describe)*
Kirschner wires are indicated for fixation of bone fractures, bone reconstruction, and as guide pins for insertion of other implants. The size of Kirschner wire should be adapted to the specific indications.

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)*

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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510(k) Summary

[As Required by 21 CFR 807.92]

(a)(1)	Submitted By:	PRECIFIT MEDICAL LTD
	Address:	951 Aviation Pkwy Ste 100, Morrisville, NORTH CAROLINA, 27560
	Phone:	901-433-1990
	Fax:	901-433-1989
	Date:	November 22, 2016
	Contact Persons	
	Primary:	Kellen Hills (Orchid Design Consulting)
	Secondary:	Eric Wu (Precifit Medical Ltd)
(a)(2)	Proprietary Name:	Precifit Medical Kirschner Wire
	Common Name:	Orthopedic wire
	Classification Name and Reference:	21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
	Product Code:	HTY, JDW
(a)(3)	Predicate Devices:	
	Primary:	In2Bones® Kirschner wire (K153204);

(a)(4) Device Description:

The Precifit Medical Kirschner wire is a stainless steel (316LVM) wire available with two point styles: smooth and threaded. The wires are available in various diameters (1.0 - 2.5mm) and lengths (120 – 200mm). One end is fixed on standard surgical power tool equipment for insertion. The Precifit Medical Kirschner wire is supplied non-sterile to be sterilized by the end user. It is intended for single use only.

The purpose of this submission is to gain initial marketing authorization in the United States.

(a)(5) Indications for Use:

Kirschner wires are indicated for fixation of bone fractures, bone reconstruction, and as guide pins for insertion of other implants. The size of Kirschner wire should be adapted to the specific indications.

(a)(6) Comparison of Technological Characteristics:

The Precifit Medical Kirschner wire is identical in intended use and 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 Precifit Medical Kirschner wires conform to the international standard ISO 5838-1 (2013). Therefore, no additional mechanical testing is required

(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 Precifit Medical Kirschner wire demonstrates substantial equivalence to the identified predicate device.