Dear Patricia Donnard:

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,

Katherine D. Kavlock -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
BePOD® EZ Weil Screws

Indications for Use (Describe)

BePOD® EZ Weil screws are designed for the following indication:

- Treatment of metatarsalgia on the lateral metatarsal shafts (side toes), by Weil osteosynthesis, following osteotomies carried out:
  - by the opened surgery (standard Weil) technique,
  - by the DMMO percutaneous technique (Distal Metatarsal Mini Invasive Osteotomy).

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.

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.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA)
Staff PRAStaff@fda.hhs.gov

“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

This summary of 510(k) safety and effectiveness information is being submitted in accordance to the requirements of 21 CFR 807.92.

Date: September 06, 2017

The assigned 510(k) number is: K163710

Applicant
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Company Contact
Patricia Donnard, Regulatory Affairs Manager
Tel: (+33) 2.98.55.68.95

Product

Trade name: BePOD® EZ Weil Screws

Common name: Screw, Fixation, Bone

Classification: Smooth or threaded metallic bone fixation fastener
Panel: Orthopedic
Product Code: HWC
Regulation Number: 888.3040
Device Class: II

Information on predicate devices to which substantial equivalence is claimed:

Manufacturer: FHI
Device Trade Name: Snap Off Screws
510 (k): K041456

Manufacturer: Newdeal (Now Integra)
Device Trade Name: SPIN Snap off Screws
510 (k): K011946
Reference devices

Manufacturer: FHI
Device Trade Name: ARROW Reverse Shoulder System
510 (k): K112193

Manufacturer: FHI
Device Trade Name: CoLS Fixation System
510 (k): K120740

Device Description

The BePOD® EZ Weil Screws are threaded titanium screws which are self-drilling and self-tapping designed for use in the foot. Once completely implanted, the screw is designed so the surgeon can snap off the introducer at the snap off axis.

The BePOD® EZ Weil Screws is intended to be implanted using the dedicated instrumentation supplied by the manufacturer.

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  - by the DMMO percutaneous technique (Distal Metatarsal Mini Invasive Osteotomy).

Comparison of Technological Characteristics

The BePOD® EZ Weil Screws and the above selected predicate devices have the same intended use and similar indications for use and share the following similarities:
- they are made out of the same materials,
- they are available in similar ranges of sizes,
- they bear design features similarities.

Non-Clinical testing

Engineering Analysis was performed to compare the subject and predicate screws. Bacterial endotoxin levels were evaluated using LAL pyrogen testing.
**Substantial Equivalence**

The substantial equivalence of our product, when compared to the selected predicate devices, has been established through the companion of indications for use, material, range of size, and design features.

**Conclusion**

Following the examination of all the above mentioned information, we believe that the BePOD® EZ Weil Screws are substantially equivalent to the selected predicate devices.