DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 4, 2017

Fournitures Hospitalières Industrie
Patricia Donnard
Regulatory Affairs Manager
Zi De Kernevez - 6 Rue Nobel
Quimper, 29000 FR

Re: K170040
Trade/Device Name: BePOD® Cannulated Arthrodesis Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: December 27, 2016
Received: January 5, 2017

Dear Ms. 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,

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)*
K170040

Device Name

BePOD Cannulated Arthrodesis Screws

Indications for Use *(Describe)*

Arthrodesis cannulated screws are designed for the following indication:

Arthrodesis of the metatarsal-phalangeal joint of the big toe.

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 of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance to the requirements of SDMA 1990 and 21 CFR 807.92.

Date: April 3, 2017
The assigned 510(k) number is: K170040

Applicant

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Product

Trade name: BePOD® Cannulated Arthrodesis Screws

Common name: Smooth or threaded metallic bone fixation fastener

Classification: The BePOD® Cannulated Arthrodesis Screws components are included in the following classifications: Screw, Fixation, Bone.
Regulation Description: Smooth or threaded metallic bone fixation fastener
Panel: Orthopedic
Product Code: HWC
Regulation Number : 888.3040
Device Class : II

Predicate/ Legally Marketed Devices
Information on devices to which substantial equivalence is claimed:

Manufacturer:	Fournitures Hospitalières Industrie
Device Trade Name:	Cannulated Screws
510 (k):	K070617

Manufacturer:	Arthrex
Device Trade Name:	FT Compression Screws
510 (k):	K132217

Reference Device

Manufacturer:	Fournitures Hospitalières Industrie
Device Trade Name:	CoLS Fixation System
510 (k):	K120740

The CoLS Fixation System is used to support the substantial equivalence

Device Description
BePOD® Cannulated Arthrodesis Screws includes the following elements:
BePOD® Arthrodesis cannulated screws

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

Indications for Use/ Intended Use
Be POD Arthrodesis cannulated screws are designed for the following indication:
- Arthrodesis of the metatarsal-phalangeal joint of the big toe.

Comparison of Technological Characteristics
The BePOD® Cannulated Arthrodesis Screws and the above selected predicate devices have the same intended use and substantial 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.

Performance
The BePOD® Cannulated Arthrodesis Screws are identical in materials and size of the predicates selected.
The LAL testing meets the specified 20EU/device limit.

Risks to health have been addressed through the specified materials, processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations.

Substantial Equivalence
The substantial equivalence of our product, when compared to the selected predicate devices and reference device, has been established following manufacturers' commercial documents, 510(k) submission's information available on FDA's website.

The analysis of these technical data allows us to submit the BePOD® Cannulated Arthrodesis Screws as being substantially equivalent to the already cleared predicate devices and reference device.

Conclusion
Following the examination of all the above mentioned information, we believe that the BePOD® Cannulated Arthrodesis Screw is substantially equivalent to the selected predicate devices in terms of design, ranges of sizes, materials, intended use, safety and effectiveness.
The BePOD® Cannulated Arthrodesis Screw is also substantially equivalent to the reference device.