



Food and Drug Administration  
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Silver Spring, MD 20993-0002

Fournitures Hospitalieres Industrie  
Patricia Donnard  
Regulatory Affairs Manager  
Zi De Kernevez - 6 Rue Nobel  
29000 Quimper  
France

September 14, 2017

Re: K163148

Trade/Device Name: BePOD® Foot Screws  
Regulation Number: 21 CFR 888.3040  
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener  
Regulatory Class: Class II  
Product Code: HWC  
Dated: July 28, 2017  
Received: August 18, 2017

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,

**Mark N. Melkerson -S**

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

Enclosure

## Indications for Use

510(k) Number (if known)  
K163148

Device Name  
BePOD Foot Screws

### Indications for Use (Describe)

BePOD 3A cannulated screws are designed for the following indications:

- Treatment of Hallux Valgus of the first metatarsal shaft (big toe) by compressive osteosynthesis, following distal and proximal metatarsal and phalangeal osteotomy.
- Compressive osteosynthesis of fractures of several bones in the forefoot.

BePOD percutaneous cannulated screws are designed for the following indications:

- Treatment of Hallux Valgus of the first metatarsal shaft (big toe) by compressive osteosynthesis, following distal and proximal metatarsal and phalangeal osteotomy.
- Compressive osteosynthesis of fractures of several bones in the forefoot.

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

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

**Date prepared:** September 12, 2017

**The assigned 510(k) number is: K163148**

**Applicant**

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**Company Contact**

Patricia DONNARD, Regulatory Affairs Manager  
Tel: (+33) 2.98.55.68.95

**Product**

**Trade name:**

BePOD<sup>®</sup> Foot 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:** SBI (Acquired by Stryker in US)  
**Device Trade Name:** Auto<sup>®</sup> Fix Screws  
**510 (k):** K052576

## Reference devices

**Manufacturer:** FH Industrie  
**Device Trade Name:** BePOD<sup>®</sup> Cannulated Arthrodesis screws  
**510 (k):** K170040

**Manufacturer:** FH Industrie  
**Device Trade Name:** CALCANAIL Fracture  
**510 (k):** K150463

## Device Description

BePOD<sup>®</sup> Foot Screws includes the following elements:

- BePOD<sup>®</sup> 3A cannulated screws
- BePOD<sup>®</sup> percutaneous cannulated screws

The BePOD<sup>®</sup> Foot Screws is intended to be implanted using the dedicated instrumentation supplied by the manufacturer.

## Indications for Use

BePOD<sup>®</sup> 3A cannulated screws are designed for the following indications:

- Treatment of Hallux Valgus of the first metatarsal shaft (big toe) by compressive osteosynthesis, following distal and proximal metatarsal and phalangeal osteotomy.
- Compressive osteosynthesis of fractures of several bones in the forefoot.

BePOD<sup>®</sup> percutaneous cannulated screws are designed for the following indications:

- Treatment of Hallux Valgus of the first metatarsal shaft (big toe) by compressive osteosynthesis, following distal and proximal metatarsal and phalangeal osteotomy.
- Compressive osteosynthesis of fractures of several bones in the forefoot.

## Comparison of Technological Characteristics

The BePOD<sup>®</sup> Foot 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<sup>®</sup> Foot Screws are identical in materials and size of the predicates selected.

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, 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<sup>®</sup> Foot Screws as being substantially equivalent to the already cleared predicate devices.

### **Conclusion**

Following the examination of all the above mentioned information, we believe that the BePOD<sup>®</sup> Foot Screws is substantially equivalent to the selected predicate devices in terms of design, ranges of sizes, materials, intended use, and safety and effectiveness.