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**Section 510(k)
Premarket Notification**

Summary of Safety and Effectiveness Information

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

Device Trade Name: EZ-Fix™ Proximal Humeral Intramedullary Rod System

Common Name: Intramedullary Rods

Registration Number: 888.3020

Classification Name: Rod, Fixation, Intramedullary and Accessories

Establishment Name & Registration Number:

Name: Biodynamic Technologies, Inc.
East Newport Center Drive
Deerfield Beach, Florida 33442
(305) 421-3166 (305) 570-6368 FAX

Number: 1035157

Contact Person:

Danny Hodgeman
Biodynamic Technologies, Inc.
East Newport Center Drive
Deerfield Beach, Florida 33442
(305) 421-3166 (305) 570-6368 FAX

Classification:

Device Class: Class II

Classification Panel: Orthopedic

Special Controls:

Not applicable to this device.

Device Description:

The EZ-Fix™ Proximal Humeral Intramedullary Rod is an internal skeletal fixation device indicated for intramedullary use to stabilize fractures of the proximal humerus. The device has been engineered for ease of use and the ability to accommodate a wide variety of proximal humeral fractures.

The EZ-Fix™ Humeral Rod is cylindrical and available in 9mm, 11mm, 13mm and 15mm diameters and is approximately 155mm in length. Proximally there are four screw holes for capturing and stabilizing humeral head fragments. Most proximally, the EZ-Fix™ Humeral Rod accepts a 6.5mm cannulated screw. Two holes, one 60 degrees anterior and one 60 degrees posterior from the lateral side, accept 5mm bone screws. The most distal hole also accepts a 5mm bone screw and is aligned laterally with the most proximal screw hole.

In addition to the four proximal holes in the 11mm, 13mm and 15mm rods, there are four suture holes proximally to attach soft tissues.

The EZ-Fix™ Humeral Rod is tri-slotted distally allowing the rod to collapse and accommodate anatomical variances. These three slots are of different lengths and extend from the distal end of the rod to just below the four proximal screw holes.

The EZ-Fix™ Humeral Rod has shallow grooves situated below the screw holes and extending lengthwise for ease of implantation without reaming, enhanced flexibility and rotational stability.

An insertion/extraction instrumentation attachment hole is located in the proximal end of the rod. This threaded hole is protected by a titanium alloy (Ti-6AL-4V) capscrew, disallowing soft tissue ingrowth post implantation.

The EZ-Fix™ Humeral Rod is titanium alloy (Ti-6AL-4V) for biocompatibility and strength.

Substantially Equivalent Devices:

Orthologic® OrthoNail® Humeral Intramedullary Fixation Device

Acumed™ Polarus® Proximal Humeral Fixation System

Applied Osteo Systems True/Flex™ Fixation Device.

Howmedica Seidel™ Humeral Locking Nail System

Comparison to Predicate Device:

The EZ-Fix™ Humeral Rod is substantially equivalent to the OrthoNail®, the Polarus®, and the True/Flex™ in that it is manufactured from titanium or titanium alloy. Like the OrthoNail®, the Polarus®, and the Seidel™, the EZ-Fix™ is of a cylindrical configuration proximally.

The EZ-Fix™ is indicated for proximal humeral fractures as is the OrthoNail®, the Polarus®, and the Seidel™. Like the OrthoNail®, the Polarus®, and the Seidel™, the

EZ-Fix™ has screw holes for fixation. In addition, the EZ-Fix™ has suture holes proximal like the OrthoNail®.

The EZ-Fix™ is equivalent to the True/Flex™ in that reaming is not required and neither devices are cannulated. Like the OrthoNail®, the EZ-Fix™ threaded insertion/extraction hole is protected by a titanium alloy capscrew, disallowing soft tissue ingrowth post implantation.

Packaging:

Sterile

The EZ-Fix™ Proximal Humeral Intramedullary Rods are packaged in a blister package consisting of a thermoformed inner tray that contains the EZ-Fix™ Rod. This tray is protected by an outer thermoformed tray that is sealed by TYVEK CR-27. The outer TYVEK cover is labeled and has affixed to it the Patient Chart Labels. Both the inner and outer trays when sealed with the TYVEK cover are enclosed in a box that is sealed and indicates the sterility of the contents. Packaging material consists of .025 BT/CTD PETG, WEB#1:CTD 1073B TYVEK CR-27.

Non-Sterile

The EZ-Fix™ Proximal Humeral Intramedullary Rod System includes EZ-Fix™ humeral rods and instrumentation and is made available non-sterile. Steam autoclavable sterilization trays have been designed to contain the EZ-Fix™ Rod System and maintain adequate separation of the implants and instruments. Sterilization cycles should be followed appropriately to achieve a 10⁻⁶ sterility assurance level (SAL).

Sterilization / Re-sterilization:

Sterile

- The EZ-Fix™ Proximal Humeral Intramedullary Rod may be supplied sterile.
- Sterilization is achieved by means of gamma radiation.
- Sterilization complies with ANSI/AAMI/ISO 11137-1994 practices.
- 10% of each production lot of EZ-Fix™ kits are tested (6% for bacteriostasis - fungistasis studies and 4% for bioburden recovery determination)
- The EZ-Fix™ is packaged in a blister package consisting of a thermoformed inner tray that contains the EZ-Fix™ Rod. This tray is protected by an outer thermoformed tray that is sealed by TYVEK CR-27. The outer TYVEK cover is labeled and has affixed to it the Patient Chart Labels. Both the inner and outer trays when sealed with the TYVEK cover are enclosed in a box that is sealed and indicates the sterility of the contents. Packaging material consists of .025 BT/CTD PETG, WEB#1:CTD 1073B TYVEK CR-27.
- The radiation dose is based on the ANSI/AAMI/ISO 11137.1994 dose setting.
- Sterilization Assurance Level (SAL) is 10⁻⁶.
- Sterilization process used is Cobalt 60.
- The EZ-Fix™ is non-pyrogenic. Pyrogenicity testing of the EZ-Fix™ to determine level of endotoxin performed using LAL (Limulus Amebocyte Lysate) method.

Non-Sterile

- The EZ-Fix™ Humeral Intramedullary Rods and all instrumentation may be supplied non-sterile.
- Steam autoclavable sterilization trays have been designed to contain the EZ-Fix™ Rod System and maintain adequate separation of the implants and instruments.
- Sterilization cycles should be followed appropriately to achieve a 10⁻⁶ sterility assurance level (SAL).
- See Appendix I for Sterilization Procedure
- The EZ-Fix™ is non-pyrogenic. Pyrogenicity testing of the EZ-Fix™ to determine level of endotoxin performed using LAL (Limulus Amebocyte Lysate) method.

Testing:

The EZ-Fix™ Proximal Humeral IM Rod has been tested by the University of Miami Biomechanics Laboratory at Mount Sinai in Miami Beach, Florida, based upon ASTM test standards for intermedullary rods (F383). Test results proved the rods to be of sound design.

Equivalence :

These test values are identical to those obtained on the referenced equivalent.

Conclusion:

Based on the materials, intended uses, design, testing, and manufacturing, the EZ Fix™ Proximal Humeral Intramedullary Rod System is equivalent to the referenced legally marketed comparison devices. The feature comparison chart below graphically demonstrates equivalence.

Comparison Table:

EZ-Fix™	OrthoNail®	Polarus®	True/Flex™	Seldel™	Substantial Equivalence
<u>Materials</u>					
Titanium Alloy	Titanium Alloy	Titanium	Titanium Alloy	Stainless Steel	Yes
<u>Geometry</u>					
Cylindrical	Cylindrical/Flat	Cylindrical	Star Shaped	Cylindrical	Yes
<u>Intended Use</u>					
Single Use Proximal Humeral Fractures	Single Use Prox/Distal Humeral Fractures	Single Use Proximal Humeral Fractures	Single Use Mid/Distal Humeral Fractures	Single Use Prox/Mid Shaft Humeral Fractures	Yes
<u>Performance Standards</u>					
ASTM	ASTM	ASTM	ASTM	ASTM	Yes
<u>Fixation</u>					
Interference Optional Screw Holes	Interference Optional Screw Holes	Interference Optional Screw Holes	Interference Mechanism	Interference Mechanism	Yes
<u>Preparation (Reaming)</u>					
Optional	Yes	Yes	No	Yes	Yes
<u>Cannulated</u>					
No	Yes	Yes	No	Yes	Yes
<u>Sterile</u>					
Sterile Non-Sterile	Non-Sterile	Sterile	Sterile	Sterile	Yes