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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™ Midshaft 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.
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Classification:

Device Class: Class II

Classification Panel: Orthopedic

Special Controls:

Not applicable to this device.

Device Description:

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

The EZ-Fix™ Midshaft Humeral IM Rod System is substantially equivalent to the **Orthologic® OrthoNail® Humeral Intramedullary Fixation Device**, the **Applied Osteo Systems True/Flex™ Fixation Device**, the **Howmedica Seidel™ Humeral Locking Nail System**, and the **Howmedica Alta®Humeral Rod.**

The EZ-Fix™ Midshaft Humeral Rod is cylindrical and available in 9mm, 11mm and 13mm diameters. The 9mm rod reduces to 7mm distally and is available in 200mm and 250mm lengths. The 11mm rod reduces to 9mm distally and is available in 200mm and 250mm lengths. The 13mm rod reduces to 11mm distally and is available in 200mm and 250mm lengths. Three screw holes proximally accept 5mm bone screws. Tuberosity fragments can be stabilized by transfixing screws. Two holes distally accept 3.5mm screws to capture and secure distal fragments or to enhance rotational stability.

The EZ-Fix™ Midshaft Humeral Rod has shallow grooves situated from the beginning of the taper and extending lengthwise for ease of implantation, 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™ Midshaft Humeral Rod is titanium alloy (TI-6AL-4V) for biocompatibility and strength.

Substantially Equivalent Devices:

Orthologic® OrthoNail® Humeral Intramedullary Fixation Device
See Appendix III for promotional materials for the comparison device.

Applied Osteo Systems True/Flex™
See Appendix III for promotional materials for the comparison device.

Howmedica Seidel™ Humeral Locking Nail System
See Appendix III for promotional materials for the comparison device.

Howmedica Alta®Humeral Rod
See Appendix III for promotional materials for the comparison device.

Comparison to Predicate Device:

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

The EZ-Fix™ is indicated for Midshaft Humeral fractures as is the OrthoNail®, the True/Flex™, the Seidel™, and the Alta®. Like the OrthoNail®, the Seidel™, and the Alta®, the EZ-Fix™ has screw holes for fixation.

The EZ-Fix™ is equivalent to OrthoNail®, the Alta™, and the Seidel in that it is 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™ Midshaft 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™ Midshaft Humeral Intramedullary Rod System includes EZ-Fix™ midshafts 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™ Midshaft 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™ Midshaft 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®	Alta™	True/Flex™	Seidel™	Substantial Equivalence
Materials					
Titanium Alloy	Titanium Alloy	Titanium Alloy	Titanium Alloy	Stainless Steel	Yes
Geometry					
Cylindrical	Cylindrical/Flat	Cylindrical	Star Shaped	Cylindrical	Yes
Intended Use					
Single Use Midshaft Humeral Fractures	Single Use Prox/Distal Humeral Fractures	Single Use Midshaft Humeral Fractures	Single Use Mid/Distal Humeral Fractures	Single Use Prox/Mid Shaft Humeral Fractures	Yes
Performance Standards					
ASTM	ASTM	ASTM	ASTM	ASTM	Yes
Fixation					
Interference Optional Screw Holes	Interference Optional Screw Holes	Interference Optional Screw Holes	Interference Mechanism	Interference Mechanism	Yes
Preparation (Reaming)					
Optional	Optional	Optional	No	Yes	Yes
Cannulated					
Yes	Yes	Yes/No	No	Yes	Yes
Sterile					
Sterile Non-Sterile	Non-Sterile	Sterile	Sterile	Sterile	Yes