

MAR 13 1997

Summary of Safety and Effectiveness

Encore Orthopedics®, Inc.
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Trade Name: TRUE/FIT™ Femoral Intramedullary Rod System

Common Name: Femoral intramedullary rod and modular components

Classification Name: Smooth or threaded metallic bone fixation fastener
CFR 888.3040.

Description: TRUE/FIT™ Femoral Intramedullary Rod System (Ti-6Al-4V) consists of:

1. Distal Segment
 - A. Transcorticle Interlocking Screws
2. Proximal Segments
 - A. Standard Segment
 - B. Dynamic Compression Segment
 - a. Locking Bolt
 - b. Dynamic Compression Bolt
 - c. End Caps
 - d. Transcorticle Interlocking Screws
 - C. Recon/Oblique Segment
 - a. Recon Cancellous Screws
 - b. Oblique Screws
 - c. Transcorticle Interlocking Screws

Intended Use:

TRUE/FIT™ Femoral Intramedullary Rod System is intended as an implantable device for the fixation of the following types of femoral fractures:

- a. femoral shaft fractures
- b. high and low subtrochanteric fractures of the femur (femoral shaft fractures distal to the proximal portion of the lesser trochanter)
- c. intertrochanteric femoral fractures
- d. femoral neck fractures
- e. ipsilateral femoral neck and shaft fractures

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TRUE/FIT™ Femoral Intramedullary Rod System
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Comparable Features to Predicate Device(s):

Product Name (Exhibit III)	Company	K Number
Gross/Kempff Femoral Nail	Howmedica	K813371
Russell/Taylor Femoral Nail	Richards Medical	K893377
Universal Nailing System	Synthes	K914371