DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*
K253155

Device Name
Fule Metallic Lockable Intramedullary Nail Systems

Indications for Use *(Describe)*
The Intramedullary Nail System of The Fule Metallic Lockable Intramedullary Nail is intended to provide temporary stabilization of various types of fractures, malunions and nonunion of the tibia. The nails are inserted using an open or closed technique and can be statically, dynamically and compressed locked. It is indicated for long bone fracture fixation, specifically tibial fracture fixation, which may include the following:

- Open and closed tibial fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Nonunion and malunion.

The Fule Proximal Femoral Nail Systems (PFNA System and SISF System) of the Fule Metallic Lockable Intramedullary Nail are intended for the treatment of stable and unstable fractures of the proximal femur, including pertrochanteric fractures, intertrochanteric fractures, basal neck fractures, and combinations thereof.

- Short nails (PFNA:170–240 mm / SISF: 180–240 mm):
- Pertrochanteric fractures
- Intertrochanteric fractures
- Basal neck fractures
- Combinations of these fracture types
- Long nails (PFNA:300–420 mm):
- Subtrochanteric fractures
- Pertrochanteric fractures associated with shaft fractures
- Pathologic fractures (including prophylactic use) in both trochanteric and diaphyseal regions
- Long subtrochanteric fractures
- Proximal or distal non-unions
- Malunions
- Revisions

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.

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