

K961027

510(k) SUMMARY
Orthofix® Tibial Nailing System
March 13, 1996

MAY - 8 1996

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510(k), premarket notification was in accordance with 21 CFR 807.87 and the SMDA.

1. **Submitter of 510(k)**

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2. **Name of Device:**

A. Trade/Proprietary Name:

Orthofix® Tibial Nailing System

B. Common/Usual Name:

Tibial Nailing System

C. Classification Name:

"Intramedullary Fixation Rod" (21 CFR 888.3020).

3. **Sponsor/Manufacturer:**

ORTHOFIX Srl.
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4. **Reason for Submitting the 510(k)**

This 510(k) is submitted to notify FDA of Orthofix's intention to commercially distribute its previously cleared Unreamed Tibial Nail System with additional tibial nails and instrumentation. The current system will include solid and cannulated nails for reamed and unreamed use.

5. **Device Description**

The Orthofix Tibial Nailing System includes a series of tibial nails of varying diameters and lengths, locking screws and end caps, as well as the instruments and accessories used in their implantation and removal.

The system will include tibial nails which range from 8 to 14 mm in diameter and from 240 to 440 mm in length. These nails are manufactured from surgical grade stainless steel (AISI 316L) and include both solid and cannulated constructions. Nails are included for reamed and unreamed use. The nails have a proximal bend and may contain proximal, intermediate and distal locking holes.

6. **Intended Use**

The system is indicated for fixation of the following conditions where the area requiring fixation is distal to the tibial tuberosity and at least 55 mm proximal to the distal articular surface: acute traumatic fractures; pathological fractures; delayed or non-unions; stabilization after corrective osteotomy; and bone transport.

7. **Substantial Equivalence**

The Orthofix Unreamed Tibial Nail System, K912420, originally received 510(k) clearance on September 23, 1991. Orthofix will now offer a greater selection of tibial nails. The nails will include solid and cannulated constructions for reamed and unreamed use. Additional instruments (e.g., reamers) have also been added to the system to meet the surgical requirements of the added tibial nails.

The information provided in this submission demonstrates that the Orthofix Tibial Nailing System with the additions cited remains substantially equivalent to itself and other legally marketed predicate devices, such as the Synthes' Universal & UTN Systems (K914453) and Richards' Russell Taylor System.