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OrthoLogic Corp.
Premarket Submission

OrthoNail
510(k)

K955761
510(k) SUMMARY
Tibia OrthoNail
December 15, 1995

K955761

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.

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

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2. **Name of Device:**

Trade/Proprietary Name:

Tibia OrthoNail

Common/Usual Name:

Intramedullary Fixation Device

Classification Name:

21 CFR 888.3020 "Intramedullary Fixation Rod", Class II.

3. **Legally Market Predicate Devices**

The Tibia OrthoNail is substantially equivalent to many legally marketed intramedullary fixation devices including those listed Table 1 below.

4. **Device Description**

The Tibia OrthoNail is indicated for stabilizing tibial fractures. All implanted components are manufactured from titanium alloy, 6Al-4V, conforming to ASTM F 136-92. The components include IM Nails, end caps, and instrumentation.

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The Tibia OrthoNail is a solid cylinder. The Tibia OrthoNail is available in diameters, 9 - 14 mm and in lengths of 200 - 425 mm. The device is designed to accept transfixing screws. End caps are provided. For use during insertion an Impacting Anvil is provided. An Alignment Tower is provided to ensure proper alignment of transfixation screw holes. The Anvil has an internal proximal thread for attachment of a slaphammer that is used for insertion or distraction.

Table 1
Comparison of Technological Characteristics
Predicate Devices and the Tibia OrthoNail

Manufacturer	OrthoLogic	Applied Osteo Systems	Richards
Device	OrthoNail	True/Flex	Russell-Taylor
Technologic Characteristic			
Tibial	yes	yes	yes
Solid Section	Yes	Yes	Yes
Transfixation Holes	Yes	Yes	Yes
Material	Titanium Alloy	Titanium Alloy	Stainless Steel
Diameter	9 - 14mm	9, 10 mm	11-14 mm
Length	200 - 425 mm	285 - 390mm	285 - 380 mm

Based on the information provided, the Tibia OrthoNail is substantially equivalent to legally marketed predicate devices.