I.T.S. GmbH
Florian Grill
Head of Quality & Regulatory Affairs, Head of R&D
Autal 28
Lassnitzhoehe, Styria 8301
Austria

February 12, 2024

Re: K233134
Trade/Device Name: I.T.S. INS Proximal Femur Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB, HWC
Dated: January 11, 2024
Received: January 11, 2024

Dear Florian Grill:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph P. Russell -S

Digitally signed by Joseph P. Russell -S
Date: 2024.02.12 14:12:32 -05'00'

for: Farzana Sharmin, PhD
Assistant Director
DHT6A: Division of Joint Arthroplasty Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233134

Device Name
I.T.S. INS Proximal Femur Nail

Indications for Use *(Describe)*
The indications for the I.T.S. Intramedullary Nailing System (INS) - Proximal Femur include intramedullary treatment of fractures and stabilization after tumor resection in the area of the proximal femur, as well as combinations that additionally affect the shaft area using the long nails.

The indications for use of the I.T.S. INS Proximal Femur include:

All Nails:
• Stable and unstable pertrochanteric fractures
• Intertrochanteric fractures
• Combinations of fractures listed above

Additionally for Long Nails:
• Subtrochanteric fractures
• Proximal fractures as listed above associated with shaft fractures
• Pathological fractures in regions as listed above
• Nonunions and malunions in regions as listed above

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In Accordance with 21 CFR 807.92 of the Federal Code of Regulations
510(k) Summary

NAME OF FIRM: I.T.S. GmbH
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www.its-implant.com

510(k) FIRM CONTACT: Jennifer Hadfield
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TRADE NAME: **I.T.S. INS Proximal Femur Nail**

DATE: February 11, 2024

COMMON NAME: Rod, fixation, intramedullary and accessories
Screw, fixation, bone

REGULATORY CLASS: Classification Name: Intramedullary Fixation Rod / Smooth or threaded metallic bone fixation fastener

Classification: 21 CFR 888.3020 / 888.3040

Device Class: Class II

DEVICE PRODUCT CODE: HSB HWC

SUBSTANTIAL EQUIVALENCE:

PRIMARY PREDICATE REFERENCE DEVICES
Stryker – Gamma3 System **(K200869)**
Stryker – Gamma4 System **(K213328)**
Smith & Nephew – Intertan (**K040212**)
Synthes De Puy – Proximal Femoral Nail (**K970097**)
Orthofix – Chimaera Hip Fracture System (**K161466**)

DEVICE DESCRIPTION: The I.T.S. INS Proximal Femur Nail consists of the following implants:

1) Nails:

The Proximal Femur Nails are designed for the treatment of femoral fractures. The Femur Nails are available in distal diameters ranging from 9 to 14mm and lengths of 180mm (short nail), 240mm (intermediate nail), and 260 to 480mm in 20mm increments (long nail). 180mm and 240mm nails have a single, oblong hole distally, while all nails with a length over 260 have a round hole, an oblong hole and another round hole for distal fixation. The oblong hole

allows for both static and dynamic locking configurations. All Trochanteric Nails are locked proximally with a Lag Screw. The set screw engages with the lag screw and allows translation while preventing rotation. Endcaps close the top of the nail and are available in 0mm, 5mm, 10mm, 15mm and 20mm lengths.

2) Lag Screw

Lag screws are cannulated with a major diameter of 10.5mm and lengths ranging from 70mm to 130mm in 5mm increments. They are available in titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

3) Set Screw

There are two types of set screws available. Inferior short and standard with a diameter of 6.6mm. The Length of the inferior short version is 45mm and the standard lengths are 70 to 130mm in 5mm increments. They are available in titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

4) Distal Cortical Locking Screw

Distal locking screws are fully threaded, with a diameter of 5.0mm and lengths ranging from 25mm to 120mm in 5mm increments (2.5mm increments available from 25-70mm). They are available in titanium alloy (Ti-6Al-4V ELI) per ASTM F136.

5) Instrumentation

I.T.S. INS Proximal Femoral Nail Instrumentation consists of implant-specific targeting devices which help facilitate insertion of the nails, lag screws, and distal locking screws. Targeting devices are manufactured from stainless steel and carbon fibre reinforced PEEK. Other instrumentation includes drills, drill guides, k-wires and screwdrivers.

All nails and screws are provided **Sterile** for **single-use.**

INDICATION FOR USE: The indications for the I.T.S. Intramedullary Nailing System (INS) - Proximal Femur include intramedullary treatment of fractures and stabilization after tumor resection in the area of the proximal femur, as well as combinations that additionally affect the shaft area using the long nails.

The indications for use of the I.T.S. INS Proximal Femur include:
All Nails:
• Stable and unstable pertrochanteric fractures
• Intertrochanteric fractures
• Combinations of fractures listed above

Additionally for Long Nails:
• Subtrochanteric fractures
• Proximal fractures as listed above associated with shaft fractures
• Pathological fractures in regions as listed above
• Nonunions and malunions in regions as listed above

CLINICAL TESTING:	Clinical data was not required for this submission.
NON-CLINICAL TESTING:	The following non-clinical laboratory testing was performed to establishing equivalence to predicate, including: • Fatigue Testing of the nail screw construct • Performance testing following the consensus standards ASTM F543 & ASTM F1264 Testing demonstrated that the I.T.S. INS Proximal Femoral Nail is substantially equivalent in mechanical performance to the predicate device.
SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:	The I.T.S.INS Proximal Femur Nail is **substantially equivalent** in material, geometry, design, indications and operational principles to the predicate systems legally marketed in the US listed above.
CONCLUSIONS:	Based on the **similarity** in material, geometry, design, indications and operational principles, as well as both the Engineering Analysis and Performance Testing, the I.T.S. INS Proximal Femur Nail has been demonstrated to be **substantially equivalent** (SE) to the predicate devices.