June 16, 2026

I.T.S. GmbH
% Mindy Mccann
VP North America & Principal Consultant
Qserve Group, US, Inc.
350 S Main St.
Suite 309
Doylestown, Pennsylvania 18901

Re: K260958
Trade/Device Name: I.T.S. Clavicle Plates with Angular Stability; I.T.S. Volar Radius Plate with Angular Stability; I.T.S. Humeral Head Plate with Angular Stability; I.T.S. FR.O.H. Calcaneus Repair System; I.T.S. Pilonplate with Angular Stability; I.T.S. Olecranonplate with Angular Stability; I.T.S. Straight Plate with Angular Stability; I.T.S. Screw System; I.T.S. PRS Sacral Rod System; I.T.S. Fibula Plate PROlock with Angular Stability; I.T.S. Distal Humeral Plates with Angular Stability; I.T.S. LRS (Locking Reconstruction System) - DFL (Distal Femur Locking) & PTL (Proximal Lateral Tibia Locking); I.T.S. Ulna Locking Plates - (DUL & UOL) Systems; I.T.S. FLS - Foot Locking Plates System; I.T.S. HCS - Headless Compression Screw System; I.T.S. HOL - Hallux Osteotomy Locking Plate; I.T.S. Twist-Off Screws; I.T.S. Hand Locking Plates System - HLS; I.T.S. Pelvic Reconstruction System (PRS RX & PRS Phoenix); I.T.S. CTN - Cannulated Tibia Nail System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC, HSB
Dated: March 23, 2026
Received: March 23, 2026

Dear Mindy Mccann:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
Assistant Director
DHT6C: Division of Restorative,
Repair, and Trauma Devices
OHT6: Office of Orthopedic Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260958 ?

Please provide the device trade name(s). ?

I.T.S. Clavicle Plates with Angular Stability;
I.T.S. Volar Radius Plate with Angular Stability;
I.T.S. Humeral Head Plate with Angular Stability;
I.T.S. FR.O.H. Calcaneus Repair System;
I.T.S. Pilonplate with Angular Stability;
I.T.S. Olecranonplate with Angular Stability;
I.T.S. Straight Plate with Angular Stability;
I.T.S. Screw System;
I.T.S. PRS Sacral Rod System;
I.T.S. Fibula Plate PROlock with Angular Stability;
I.T.S. Distal Humeral Plates with Angular Stability;
I.T.S. LRS (Locking Reconstruction System) - DFL (Distal Femur Locking) & PTL (Proximal Lateral Tibia Locking);
I.T.S. Ulna Locking Plates - (DUL & UOL) Systems;
I.T.S. FLS - Foot Locking Plates System;
I.T.S. HCS - Headless Compression Screw System;
I.T.S. HOL - Hallux Osteotomy Locking Plate;
I.T.S. Twist-Off Screws;
I.T.S. Hand Locking Plates System - HLS;
I.T.S. Pelvic Reconstruction System (PRS RX & PRS Phoenix);
I.T.S. CTN - Cannulated Tibia Nail System

Please provide your Indications for Use below. ?

The I.T.S. Clavicle Plates with Angular Stability is a titanium implant fracture fixation system for repairing fractures located from the middle third to the distal third of the clavicle. Indications for Use include metaphyseal and diaphyseal fracture fixation of acute fractures, malunions, and non-unions of the clavicle. Other indications include corrective osteotomy and open and closed fractures. All fractures of the clavicle in metaphyseal and diaphyseal areas. Hygienisaton of pseudo-arthroses with or without spongiosal graft. Corrective osteotomy. Open and closed fractures.

The I.T.S. Volar Radius Plates with Angular Stability is a titanium implant fracture fixation system for distal radius fractures of the wrist. Indications for Use include comminuted extra and intra-articular distal radius fractures, failed original fracture fixation, osteotomy and repair of a distal radius malunion, and comminuted volar shearing fractures. Complex intra-articular fractures of the distal radius. Complex extra-articular fractures of the distal radius. Osteotomies of the distal radius.

The I.T.S. Humeral Head Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the proximal humerus in the shoulder. Indications for Use include fracture and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone. All stable and unstable humerus fractures with or without shaft involvement. Fractures of the greater or lesser tuberosities. Repair of the greater tuberosity following prior fixation failure or tuberosity “escape”. Delayed or nonunion of the proximal humerus. Fixation following osteotomy of proximal humeral malunion. Displaced two, three and four part fracture of the proximal humerus. Displaced anterior and posterior fractures of the proximal humerus and greater tuberosity. Nonunion of two, three and four part fractures of the proximal humerus. Nonunion of anterior and posterior fracture-dislocations of the proximal humerus and

greater tuberosity. Dislocated, unstable 2, 3 and 4-segment fractures of the humeral head. Valgus-impacted 4-segment fractures of the humeral head. Non-union of the humeral head.

The I.T.S. FR.O.H. Calcaneus Repair System is a titanium implant fracture fixation system for repairing fractures located in the calcaneus heel bone of the foot. Indications for Use include: Intra and extra-articular fracture(s) of the calcaneus, corrective osteotomy, joint depression, non-displaced and tongue type, severely comminuted fractures, multifragmentary fractures, revision procedures, joint fusion, stabilization and fixation of fresh fractures, reconstruction of the calcaneus bones, and open and closed fractures of the calcaneus. The system can be used in both adult and pediatric patients. Complex Fractures of the Calcaneus. All intra-articular fractures with relevant joint distortion and comminution zone in which a semi-operative procedure (screws, drill wires) does not raise expectations of exact repositioning. Fractures of the sustentaculum tali.

The I.T.S. Pilon Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the distal tibia in the leg. Indications for Use include fixation of complex intra- and extraarticular fractures, osteotomies, high medial malleollar fractures, and low boot top type rotational distal extra-articular shaft fractures of the distal tibia. Fractures of the tibial pilon of AO classification A3, especially groups C2 and C3.

The I.T.S. Olecranon Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the proximal ulna (olecranon) in the elbow. Indications for Use include fixation of complex intra- and extraarticular fractures, osteotomies, nonunions, malunions, Type 1, 2, 3, & 4 simple fractures, and Type 5a, 5b, 5c, & 6 complex fractures (comminuted) of the proximal ulna (olecranon). All fractures of the olecranon.

The intended use of the I.T.S. Straight Plates with Angular Stability is to stabilize an osteotomy or fracture of small bones, long bones, the pelvis and the calcaneus in an adult or pediatric patient. Indications for use include communted fractures, supracondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, non-unions, and mal-unions, as well, a fracture or osteotomy of the tibia, fibula, femoral condyle, acetabulum, humerus, ulna, middle hand and middle foot bones. Treatment of the calcaneal; hip arthrodesis, and provisional hole fixation.

The intended use of the I.T.S. Screw System is for corrective osteotomy or internal fracture fixation of the patella, pelvis, ankle, and long bones in an adult or pediatric patient. For the 4.0mm Cannulated Cancellous Screw indications for use are for radial and ulnar fractures, fractures of the proximal/distal humerus and of the patellas and for tendon fixation, maisonneuve injuries and disruption of the syndesmosis with bimalleolar or supramalleolar fractures and the instabilty of the talus centering. For the 6.5mm Cannulated Canncellous Screw, indications for use are for fractures of the femoral neck, tiblaplateau, of the sacrum and the articular cavity of the hip joint and the metaphyseal fractures of the distal femur and distal tbia, fixation of the ilio-sacal joint, and fusion of the foot and ankle.
For the 7.3mm Cannulated Cancellous Screw, indications for use are for fractures of the calcaneus, femoral neck, tiblaplateau, and of the sacrum and the articular cavity of the hip joint. Fusion of the foot and ankle, fixation of the Ilio-sacral joint, and metaphyseal fractures of the distal femur and distal tibia.

The intended use of the I.T.S. Pelvic Reconstruction System (PRS) is to stabilize one or more pelvic bone fractures in the pelvic ring area of the pelvis of an adult or pediatric patient. The indications for use of the I.T.S. PRS Sacral Rod System include fixation of fractures of the posterior pelvis, fixation of fractures of the posterior iliac spine, fixation of fractures of the posterior inferior iliac spine, dorsal stabilization of the posterior pelvic ring for unstable pelvic ring injuries, fixation of sacral fractures, and fracture dislocations of the sacro-iliac joint.

The I.T.S. Fibula Plate PROlock with Angular Stability is a titanium implant fracture fixation system for

repairing bone fractures located from the middle to the distal third of the fibula. Indications for Use include metaphyseal and diaphyseal fracture fixation of acute fractures, mal-unions, and non-unions of the distal fibula. Other indications include corrective osteotomy and open and closed fractures. Dislocated ankle-fractures group B+C according to Weber (with or without comminuted zones).

The I.T.S. Distal Humeral Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the distal humerus in the elbow of a pediatric or adult patient. Indications for Use include intra-articular fractures, supracondylar fractures, osteotomies, and non-unions of the distal humerus. Supra- & diacondylar upper-arm fractures.

The I.T.S. LRS Locking Reconstruction System is a titanium implant fracture fixation system for stabilizing fractures in long bones of the distal femur of all pediatric patients (less than or equal to 21 years old) or adult patient. Indications for Use include distal shaft fractures, supracondylar fractures, intra-articular fractures, metaphyseal fractures, osteotomies, nonunions and malunions of the distal femur.
The I.T.S. LRS Locking Reconstruction System is a titanium implant fracture fixation system for stabilizing fractures in long bones of the proximal lateral tibia of all pediatric patients (less than or equal to 21 years old) or adult patient. Indications for Use include proximal shaft fractures, supracondylar fractures, intra-articular fractures, metaphyseal fractures, osteotomies, nonunions and malunions of the proximal tibia.

The Indications for Use of the I.T.S. GmbH - Distal Ulna Locking (DUL) Plate Systems is to stabilize fractures in the long bone of the distal ulna of an adult patient. Fractures of the ulnar head. Multifragmentary fracture of the ulnar head. Subcapital fractures of the ulnar head. Metaphyseal comminuted fractures of the distal ulna. Combined ulnar head and ulnar shaft fractures.
The Indications for Use of the I.T.S. GmbH - Ulna Osteotomy Locking (UOL) Plate Systems is to stabilize osteotomies in the long bone of the mid-ulna of an adult patient. Impaction syndrome of the ulnar wrist. Symptomatic, post-traumatic ulnar malposition in the distal radio-ulnar joint (DRUJ). Degenrerative ulnar wrist. Correction of the ulnar positive relative to the unaffected other side up to a maximum of 6mm in one step or 13mm in two steps.

The I.T.S. FLS Foot Locking Plate System is indication for use in internal fixation, reconstruction or athrodesis of small bones including the fore, mid and hind foot and ankle. Examples of these procederes may included but are not limited to replantation, lag srew techniques, joint fusions, corrective osteotomies, and treatment of fracture. Metatarsal fractures. TMT I-V Arthrodesis, MTP I-V Arthrodesis, TN, CC Arthrodesis, Corrective Osteotomies.

The I.T.S. HCS - Headless Compression Screw System for sizes of 3.5mm or smaller is indicated for use in fixation small bone fractures or for small bone reconstruction including: mono or bicorlical osteotomies in the foot or hand; distal or proximal metatarsal or metacarpal osteotomies; weil osteotomy; fusion of the first metatarsalphalangeal joint and interphalageal joint: fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.); Akin type osteotomy; distal radius fractures (articular fragments). ulnar styloid fractures, radial head fractures, capitellum fractures, humeral head fractures, glenoid fractures, intercarpal distal and proximal fusions, malleolar fractures, patellar fractures, osteochondral fractures, talonavicular fusions, tibeo-talar fusions, and cuboid fusions.
And for sizes 4.3mmn or larger is indicated for use for fractures, corrective osteotomies, pseudoarthrosis, degenerative transformations of long bones in the hindfoot and large bone intra-articular fractures of the humerus, femur and tibia. The size of the chosen compression screw should be adapted to the specific indication.

The I.T.S. HOL - Hallux Osteotomy Locking Plate System is Indicated for use as an intramedullary self-locking plate for distal metatarsal osteotomies and for Hallux Valgus osteotomies up to a corrective angle of 25°. Intramedullary, self locking plate for distal metatarsal osteotomies. Hallux Valgus osteotomies up to a corrective angle of 25°.

The I.T.S. Twist-Off Screw System is indicated for use for small bone fixation of bone fractures or for bone reconstruction. Examples include small bone fragments, Weil- Osteotomy, Mono-Cortical fixation, Osteotomies and fractures fixation in the foot and hand. For treatment of fractures, corrective osteotomies, arthrodesis and degenerative transformations of small bones.

The I.T.S. Hand Locking Plate System -HLS is indicated for use in fracture fixation of: The phalanges, The metacarpal bones, The carpal bones, For arthrodesis, For corrective osteotomies and For subcapital radial head fractures.

Indications for use of the I.T.S. Pelvic Reconstruktion System (PRS Phoenix) include: Fractures involving the Posterior Wall & Posterior Column, Fractures involving the Anterior Column of the Acetabulum, Fractures involving the Quadrilateral Surface, Symphyseal Disruptions & Para-symphseal Fractures, Fractures of the ilium, Fractures of the SIJ, Dorsal neutralization plating for posterior pelvic ring fractures, Osteotomies, arthrodesis and sacroiliac joint dislocations, Revision surgery of pseudoarthroses, non-unions and mal unions.

The I.T.S. CTN – Cannulated Tibia Nail System is indicated for use in long bone tibia fracture fixation which include: Proximal, metaphyseal, epiphyseal and distal shaft fractures; Segmental, simple, compound and comminuted fractures; Transverse, oblique and spiral fractures; Surgically created defects using osteotomies, such as for leg length discrepancies or deformity; Pathologic fractures; Pseudoarthrosis, non-union, mal-union and delayed union of the tibia; Fractures involving osteopenic and osteoporotic bone; Open fractures of the tibia and; Reconstruction of the tibia after tumor resection and/or bone loss.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?
Please select the age group(s) for which the device(s) is to be used.	☐ Neonates/Newborns (Birth to < 29 days old) ☐ Infants (29 days old to < 2 years old) ☐ Children (2 years old to < 12 years old) ☐ Adolescents (12 years old to < 22 years old) ☒ Adults (22 years old and greater)	?

K260958
510(k) Submission
I.T.S. GmbH
MR Conditional

510(k) Summary

NAME OF FIRM:	I.T.S. GmbH Autal 28 Lassnitzhoehe, 8301 Austria **www.its-implant.com**
510(k) FIRM CONTACT:	Mindy Mccan Qserve Group US, Inc. 350 S Main Street, Suite 309 Doylestown, Pennsylvania, 18901, United States Tel. No. 424-271-8169 e-mail: **usagent@qservegroup.com**
TRADE NAME:	**I.T.S. Clavicle Plates with Angular Stability** **I.T.S. Volar Radius Plate with Angular Stability** **I.T.S. Humeral Head Plate with Angular Stability** **I.T.S. FR.O.H. Calcaneus Repair System** **I.T.S. Pilonplate with Angular Stability** **I.T.S. Olecranonplate with Angular Stability** **I.T.S. Straight Plate with Angular Stability** **I.T.S. Screw System** **I.T.S. PRS Sacral Rod System** **I.T.S. Fibula Plate PROlock with Angular Stability** **I.T.S. Distal Humeral Plates with Angular Stability** **I.T.S. LRS (Locking Reconstruction System) – DFL (Distal Femur Locking) & PTL (Proximal Lateral Tibia Locking)** **I.T.S. Ulna Locking Plates – (DUL & UOL) Systems** **I.T.S. FLS – Foot Locking Plates System** **I.T.S. HCS – Headless Compression Screw System** **I.T.S. HOL – Hallux Osteotomy Locking Plate** **I.T.S. Twist-Off Screws** **I.T.S. Hand Locking Plates System - HLS** **I.T.S. Pelvic Reconstruction System (PRS RX & PRS Phoenix)** **I.T.S. CTN – Cannulated Tibia Nail System**
DATE:	June 11, 2026
COMMON NAME:	Plate, Fixation, Bone, Screw, Fixation, Bone, Rod, Fixation, Intramedullary and Accessories
REGULATORY CLASS:	**Class II**
DEVICE PRODUCT CODE:	**HRS, HWC, HSB**

510(k) Submission
I.T.S. GmbH
MR Conditional

SUBSTANTIAL EQUIVALENCE:

PRIMARY PREDICATE I.T.S. Clavicle Plates with Angular Stability **(K050852)**

ADDITIONAL PREDICATES
I.T.S. Volar Radius Plate with Angular Stability **(K033756)**
I.T.S. Humeral Head Plate with Angular Stability **(K051412)**
I.T.S. FR.O.H. Calcaneus Repair System **(K051642)**
I.T.S. Pilonplate with Angular Stability **(K052011)**
I.T.S. Olecranonplate with Angular Stability **(K052368)**
I.T.S. Straight Plate with Angular Stability **(K060156)**
I.T.S. Screw System **(K060156)**
I.T.S. PRS Sacral Rod System **(K063166)**
I.T.S. Fibula Plate PROlock with Angular Stability **(K063672)**
I.T.S. Distal Humeral Plates with Angular Stability **(K080184)**
I.T.S. LRS (Locking Reconstruction System) – DFL (Distal Femur Locking) & PTL (Proximal Lateral Tibia Locking) **(K093868)**
I.T.S. Ulna Locking Plates – (DUL & UOL) Systems **(K130008)**
I.T.S. FLS – Foot Locking Plates System **(K131722)**
I.T.S. HCS – Headless Compression Screw System **(K131722)**
I.T.S. HOL – Hallux Osteotomy Locking Plate **(K131722)**
I.T.S. Twist-Off Screws **(K131722)**
I.T.S. Hand Locking Plates System – HLS **(K142418)**
I.T.S. Pelvic Reconstruction System (PRS RX & PRS Phoenix) **(K210935)**
I.T.S. CTN – Cannulated Tibia Nail System **(K132945)**

DEVICE DESCRIPTION: The purpose of this Traditional 510(k) is to add the updated MR conditional safety information to the labeling and provide performance data. The intended use, technological characteristics, function and operating principles and anatomical site for implantation of the devices remain unchanged. No modification has been made to the device material, sterilization, packaging, and the manufacturing processes of the currently marketed devices.

INDICATION FOR USE: The I.T.S. Clavicle Plates with Angular Stability is a titanium implant fracture fixation system for repairing fractures located from the middle third to the distal third of the clavicle. Indications for Use include metaphyseal and diaphyseal fracture fixation of acute fractures, malunions, and non-unions of the clavicle. Other indications include corrective osteotomy and open and closed fractures. All fractures of the clavicle in metaphyseal and diaphyseal areas. Hygienisaton of pseudo-arthroses with or without spongiosal graft. Corrective osteotomy. Open and closed fractures.

The I.T.S. Volar Radius Plates with Angular Stability is a titanium implant fracture fixation system for distal radius fractures of the wrist. Indications for Use include comminuted extra and intra-articular distal radius fractures, failed original fracture fixation, osteotomy and repair of a distal radius malunion, and comminuted volar shearing fractures. Complex intra-articular fractures of the distal radius. Complex extra-articular fractures of the distal radius. Osteotomies of the distal radius.

The I.T.S. Humeral Head Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the proximal humerus in the shoulder. Indications for Use include fracture and fracture dislocations, osteotomies, and non-unions of the proximal humerus, particularly in osteopenic bone. All stable and unstable humerus fractures with or without shaft involvement. Fractures of the greater or lesser tuberosities. Repair of the greater tuberosity following prior fixation failure or tuberosity “escape”. Delayed or nonunion of the proximal humerus. Fixation following osteotomy of proximal humeral malunion. Displaced two, three and four part fracture of

the proximal humerus. Displaced anterior and posterior fractures of the proximal humerus and greater tuberosity. Nonunion of two, three and four part fractures of the proximal humerus. Nonunion of anterior and posterior fracture-dislocations of the proximal humerus and greater tuberosity. Dislocated, unstable 2, 3 and 4-segment fractures of the humeral head. Valgus-impacted 4-segment fractures of the humeral head. Non-union of the humeral head.

The I.T.S. F.R.O.H. Calcaneus Repair System is a titanium implant fracture fixation system for repairing fractures located in the calcaneus heel bone of the foot. Indications for Use include: Intra and extra-articular fracture(s) of the calcaneus, corrective osteotomy, joint depression, non-displaced and tongue type, severely comminuted fractures, multifragmentary fractures, revision procedures, joint fusion, stabilization and fixation of fresh fractures, reconstruction of the calcaneus bones, and open and closed fractures of the calcaneus. The system can be used in both adult and pediatric patients. Complex Fractures of the Calcaneus. All intra-articular fractures with relevant joint distortion and comminution zone in which a semi-operative procedure (screws, drill wires) does not raise expectations of exact repositioning. Fractures of the sustentaculum tali.

The I.T.S. Pilon Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the distal tibia in the leg. Indications for Use include fixation of complex intra- and extraarticular fractures, osteotomies, high medial malleollar fractures, and low boot top type rotational distal extra-articular shaft fractures of the distal tibia. Fractures of the tibial pilon of AO classification A3, especially groups C2 and C3.

The I.T.S. Olecranon Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the proximal ulna (olecranon) in the elbow. Indications for Use include fixation of complex intra- and extraarticular fractures, osteotomies, nonunions, malunions, Type 1, 2, 3, & 4 simple fractures, and Type 5a, 5b, 5c, & 6 complex fractures (comminuted) of the proximal ulna (olecranon). All fractures of the olecranon.

The intended use of the I.T.S. Straight Plates with Angular Stability is to stabilize an osteotomy or fracture of small bones, long bones, the pelvis and the calcaneus in an adult or pediatric patient. Indications for use include communted fractures, supracondylar fractures, intra-articular and extra-articular condylar fractures, fractures in osteopenic bone, non-unions, and mal-unions, as well, a fracture or osteotomy of the tibia, fibula, femoral condyle, acetabulum, humerus, ulna, middle hand and middle foot bones. Treatment of the calcaneal; hip arthrodesis, and provisional hole fixation.

The intended use of the I.T.S. Screw System is for corrective osteotomy or internal fracture fixation of the patella, pelvis, ankle, and long bones in an adult or pediatric patient. For the 4.0mm Cannulated Cancellous Screw indications for use are for radial and ulnar fractures, fractures of the proximal/distal humerus and of the patellas and for tendon fixation, maisonneuve injuries and disruption of the syndesmosis with bimalleolar or supramalleolar fractures and the instabilty of the talus centering. For the 6.5mm Cannulated Canncellous Screw, indications for use are for fractures of the femoral neck, tiblaplateau, of the sacrum and the articular cavity of the hip joint and the metaphyseal fractures of the distal femur and distal tbia, fixation of the ilio-sacal joint, and fusion of the foot and ankle.
For the 7.3mm Cannulated Cancellous Screw, indications for use are for fractures of the calcaneus, femoral neck, tiblaplateau, and of the sacrum and

the articular cavity of the hip joint. Fusion of the foot and ankle, fixation of the Ilio-sacral joint, and metaphyseal fractures of the distal femur and distal tibia.

The intended use of the I.T.S. Pelvic Reconstruction System (PRS) is to stabilize one or more pelvic bone fractures in the pelvic ring area of the pelvis of an adult or pediatric patient. The indications for use of the I.T.S. PRS Sacral Rod System include fixation of fractures of the posterior pelvis, fixation of fractures of the posterior iliac spine, fixation of fractures of the posterior inferior iliac spine, dorsal stabilization of the posterior pelvic ring for unstable pelvic ring injuries, fixation of sacral fractures, and fracture dislocations of the sacro-iliac joint.

The I.T.S. Fibula Plate PROlock with Angular Stability is a titanium implant fracture fixation system for repairing bone fractures located from the middle to the distal third of the fibula. Indications for Use include metaphyseal and diaphyseal fracture fixation of acute fractures, mal-unions, and non-unions of the distal fibula. Other indications include corrective osteotomy and open and closed fractures. Dislocated ankle-fractures group B+C according to Weber (with or without comminuted zones).

The I.T.S. Distal Humeral Plates with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the distal humerus in the elbow of a pediatric or adult patient. Indications for Use include intra-articular fractures, supracondylar fractures, osteotomies, and non-unions of the distal humerus. Supra- & diacondylar upper-arm fractures.

The I.T.S. LRS Locking Reconstruction System is a titanium implant fracture fixation system for stabilizing fractures in long bones of the distal femur of all pediatric patients (less than or equal to 21 years old) or adult patient. Indications for Use include distal shaft fractures, supracondylar fractures, intra-articular fractures, metaphyseal fractures, osteotomies, nonunions and malunions of the distal femur.
The I.T.S. LRS Locking Reconstruction System is a titanium implant fracture fixation system for stabilizing fractures in long bones of the proximal lateral tibia of all pediatric patients (less than or equal to 21 years old) or adult patient. Indications for Use include proximal shaft fractures, supracondylar fractures, intra-articular fractures, metaphyseal fractures, osteotomies, nonunions and malunions of the proximal tibia.

The Indications for Use of the I.T.S. GmbH - Distal Ulna Locking (DUL) Plate Systems is to stabilize fractures in the long bone of the distal ulna of an adult patient. Fractures of the ulnar head. Multifragmentary fracture of the ulnar head. Subcapital fractures of the ulnar head. Metaphyseal comminuted fractures of the distal ulna. Combined ulnar head and ulnar shaft fractures. The Indications for Use of the I.T.S. GmbH - Ulna Osteotomy Locking (UOL) Plate Systems is to stabilize osteotomies in the long bone of the mid-ulna of an adult patient. Impaction syndrome of the ulnar wrist. Symptomatic, post-traumatic ulnar malposition in the distal radio-ulnar joint (DRUJ). Degenrerative ulnar wrist. Correction of the ulnar positive relative to the unaffected other side up to a maximum of 6mm in one step or 13mm in two steps.

The I.T.S. FLS Foot Locking Plate System is indication for use in internal fixation, reconstruction or athrodesis of small bones including the fore, mid and hind foot and ankle. Examples of these procederes may included but are not limited to replantation, lag srew techniques, joint fusions, corrective osteotomies, and treatment of fracture. Metatarsal fractures. TMT I-V

Arthrodesis, MTP I-V Arthrodesis, TN, CC Arthrodesis, Corrective Osteotomies.

The I.T.S. HCS - Headless Compression Screw System for sizes of 3.5mm or smaller is indicated for use in fixation small bone fractures or for small bone reconstruction including: mono or bicorlical osteotomies in the foot or hand; distal or proximal metatarsal or metacarpal osteotomies; weil osteotomy; fusion of the first metatarsalphalangeal joint and interphalageal joint: fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.); Akin type osteotomy; distal radius fractures (articular fragments). ulnar styloid fractures, radial head fractures, capitellum fractures, humeral head fractures, glenoid fractures, intercarpal distal and proximal fusions, malleolar fractures, patellar fractures, osteochondral fractures, talonavicular fusions, tibeo-talar fusions, and cuboid fusions. And for sizes 4.3mmn or larger is indicated for use for fractures, corrective osteotomies, pseudoarthrosis, degenerative transformations of long bones in the hindfoot and large bone intra-articular fractures of the humerus, femur and tibia. The size of the chosen compression screw should be adapted to the specific indication.

The I.T.S. HOL - Hallux Osteotomy Locking Plate System is Indicated for use as an intramedullary self-locking plate for distal metatarsal osteotomies and for Hallux Valgus osteotomies up to a corrective angle of 25°. Intramedullary, self locking plate for distal metatarsal osteotomies. Hallux Valgus osteotomies up to a corrective angle of 25°.

The I.T.S. Twist-Off Screw System is indicated for use for small bone fixation of bone fractures or for bone reconstruction. Examples include small bone fragments, Weil- Osteotomy, Mono-Cortical fixation, Osteotomies and fractures fixation in the foot and hand. For treatment of fractures, corrective osteotomies, arthrodesis and degenerative transformations of small bones.

The I.T.S. Hand Locking Plate System -HLS is indicated for use in fracture fixation of: The phalanges, The metacarpal bones, The carpal bones, For arthrodesis, For corrective osteotomies and For subcapital radial head fractures.

Indications for use of the I.T.S. Pelvic Reconstruktion System (PRS Phoenix) include: Fractures involving the Posterior Wall & Posterior Column, Fractures involving the Anterior Column of the Acetabulum, Fractures involving the Quadrilateral Surface, Symphyseal Disruptions & Para-symphseal Fractures, Fractures of the ilium, Fractures of the SIJ, Dorsal neutralization plating for posterior pelvic ring fractures, Osteotomies, arthrodesis and sacroiliac joint dislocations, Revision surgery of pseudoarthroses, non-unions and mal unions.

The I.T.S. CTN – Cannulated Tibia Nail System is indicated for use in long bone tibia fracture fixation which include:
Proximal, metaphyseal, epiphyseal and distal shaft fractures; Segmental, simple, compound and comminuted fractures; Transverse, oblique and spiral fractures; Surgically created defects using osteotomies, such as for leg length discrepancies or deformity; Pathologic fractures; Pseudoarthrosis, non-union, mal-union and delayed union of the tibia; Fractures involving osteopenic and osteoporotic bone; Open fractures of the tibia and; Reconstruction of the tibia after tumor resection and/or bone loss.

510(k) Submission
I.T.S. GmbH
MR Conditional

CLINICAL TESTING: Clinical data was not required for this submission.

NON-CLINICAL TESTING: The following non-clinically tests were performed:

- Non-clinical testing was conducted per FDA's guidance "Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment", and is provided to support the conditional safety in the MR environment including assessment of magnetically induced displacement force (ASTM F2052) and torque (ASTM F2213), radio frequency (RF) heating (ASTM F2182), image artifacts (ASTM F2119) and standard practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment (ASTM F2503).

The non-clinical performance data demonstrate that the subject devices, when exposed to the MR environment under specific MR conditions of use, raise no new questions of safety and efficacy.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS: The intended use, technological characteristics, function and operating principles and anatomical site for implantation of the devices remain unchanged. No modification has been made to the device material, sterilization, packaging, and the manufacturing processes of the currently marketed devices.

CONCLUSIONS: Based on the results of the non-clinical MRI safety testing described above, it is concluded that the subject devices are substantially equivalent to the predicate devices. The data demonstrate that the updated labeling does not alter the device performance regarding its intended use. Furthermore, the evaluation confirms that the subject devices remain as safe and effective as the predicates for their cleared indications, raising no new questions of safety or effectiveness.