April 24, 2026

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

Re: K260054
Trade/Device Name: I.T.S. PRS Phoenix II
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HTN, HWC
Dated: March 27, 2026
Received: March 27, 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.	K260054

Please provide the device trade name(s).

I.T.S. PRS Phoenix II

Please provide your Indications for Use below.

The I.T.S. PRS Phoenix II is indicated to stabilize one or more pelvic bone fractures in the pelvis in an adult patient. Indications for use of the I.T.S. PRS Phoenix II include:

- Symphyseal Disruptions & Parasymphyseal Fractures
- Disruptions of the Sacroiliac Joint
- Fractures involving the Anterior Column of the Acetabulum
- Fractures involving the Quadrilateral Surface
- Fractures involving the Posterior Wall
- Fractures involving the Posterior Column
- Dorsal neutralization plating for Posterior Pelvic Ring Fractures
- Fractures of the Acetabulum, Fractures of the Pelvic Ring, Fractures of the Ilium
- Fracture Revision surgery of pseudoarthrosis, non-unions and mal-unions

The I.T.S. PRS Phoenix II System is not intended for spinal use.

Please select the types of uses (select one or both, as applicable).

- [X] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

K260054
510(k) Submission
I.T.S. GmbH
I.T.S. PRS Phoenix II

In Accordance with 21 CFR 807.92 of the Federal Code of Regulations
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. PRS Phoenix II**

DATE: April 23th , 2026

COMMON NAME: Plate, fixation, bone, washer, bolt nut,
Screw, fixation, bone

REGULATORY CLASS: **Class II** 21 CFR 888.3030 - Single/multiple component metallic bone fixation appliance and accessories

DEVICE PRODUCT CODE: **HRS**

SUBSEQUENT PRODUCT CODE : **HTN, HWC**

SUBSTANTIAL EQUIVALENCE:

PRIMARY PREDICATE I. T.S. Pelvic Reconstruction System PRS RX & PRS Phoenix **(K210935)**

ADDITIONAL PREDICATES
I.T.S. Pelvic Reconstruction System **(K063166)**
Stryker PRO Plating System, Stryker Trauma Pelvic Set (Matta) **(K223772)**
DePuy Synthes 3.5mm Intrapelvic Acetabular System **(K221809)**
Acumed Pelvic Bone Plate System **(K122538)**

DEVICE DESCRIPTION: The I.T.S. PRS Phoenix II consists of the following implants:

- Symphysis Plate, 4-Hole
- Symphysis Plate, 6-Hole
- Biplanar Symphysis Plate
- W-Plate 4-Hole (Small Frag)
- W-Plate 4-Hole (Large Frag)
- Extended Anterior Column Plate, left/right
- H-Plate
- Anterior Column Plate, left/right
- Bridge Plate
- Base Plate
- Infrapectineal Buttress Plate, left/right
- Helical Infrapectineal Plate, left/right
- Biplanar Plate, 21-Hole, left/right
- Biplanar Plate, 23-Hole, left/right
- Spring Plate
- Rim Stabilization Plate, 4-Hole
- Rim Stabilization Plate, 6-Hole

- Posterior Wall Plate, left/right
- Global Posterior Stabilization Plate, left/right
- Posterior Column Plate, left/right
- Straight Plates
- Curved Plates
- Cortical Screw, D=2.7mm, Non-Locking
- Cortical Stabilization Screw, D=3.0mm, RH, Locking
- Cancellous Stabilization Screw, D=3.0mm, D=3.0mm, RH, Locking
- Cortical Screw, D=3.5mm, Non-locking
- Cancellous Screw, D=4.2mm, Locking
- Cancellous Screw, D=5.9mm, Non-Locking
- Cancellous Screw, D=5.9mm, Locking
- Cortical Screw, D=4.5mm, Non-Locking
- Cortical Screw, D=4.5mm, Locking

INDICATION FOR USE: The I.T.S. PRS Phoenix II is indicated to stabilize one or more pelvic bone fractures in the pelvis in an adult patient. Indications for use of the I.T.S. PRS Phoenix II include:

- Symphyseal Disruptions & Parasymphyseal Fractures
- Disruptions of the Sacroiliac Joint
- Fractures involving the Anterior Column of the Acetabulum
- Fractures involving the Quadrilateral Surface
- Fractures involving the Posterior Wall
- Fractures involving the Posterior Column
- Dorsal neutralization plating for Posterior Pelvic Ring Fractures
- Fractures of the Acetabulum, Fractures of the Pelvic Ring, Fractures of the Ilium
- Fracture Revision surgery of pseudoarthrosis, non-unions and mal-unions

The I.T.S. PRS Phoenix II system is not intended for spinal use

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

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

- FEA-simulation according to ASTM F382 to test that the subject devices can withstand the same or more load than the cleared device.
- Screws were tested according to ASTM F543 and compared to the guideline: “Orthopedic Non-Spinal Metallic Bone Screws and Washers – Performance Criteria for Safety and Performance Based Pathway”, issued on November 22, 2024
- On worst case products: Bioburden-, Sterility-, (both according to ISO 11137-1, ISO 11137-2, ISO, 11137-3) Endotoxin- (Ph. Eur. 2.6.14 / USP <85>) and Cytotoxicity-testing (ISO 10993-5) was performed to ensure sterility and an acceptable endotoxin values.
- RF-heating (according to ASTM F2182-19e2), magnetically induced displacement Force (according to ASTM F2052 – 21), magnetically induced Torque (according to ASTM F2213-17) and image Artifact evaluation and testing were performed according to ASTM F2213-17 (according to ASTM F2119 – 24) with worst case products. The subject device was compared to the evaluated worst-case products for torque, force and image artefacts. For RF-heating to products were compared to

similar geometry and size products to prove they don't present the worst case.

Testing demonstrated that the I.T.S. PRS Phoenix II is substantially equivalent in mechanical performance to the predicate device I.T.S. Pelvic Reconstruction System PRS RX & PRS Phoenix (K210935)

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS:

The I.T.S.PRS Phoenix II is **substantially equivalent** in material (all plates are made from made from the same material (Titanium according to ASTM F67 and ASTM F136, Type II anodized), geometry and design (anatomically shaped plates with similar characteristics), indications and operational principles to the primary 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.PRS Phoenix II has been demonstrated to be **substantially equivalent** (SE) to the predicate devices.