August 31, 2022

I.T.S. GmbH
c/o Jennifer Hadfield
Qserve Group US
U.S. Agent and Official Correspondent
350 S Main Street, Suite 309
Doylestown, PA 18901

Re: K210935
Trade/Device Name: I.T.S. Pelvic Reconstruction System (PRS RX & PRS Phoenix)
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, HTN
Dated: March 15, 2021
Received: March 29, 2021

Dear Jennifer Hadfield:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Shumaya Ali, M.P.H.
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

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)*
K210935

Device Name
I.T.S. Pelvic Reconstruction Systems (PRS RX & PRS Phoenix)

Indications for Use *(Describe)*
The I.T.S. Pelvic Reconstruction Systems (PRS RX & PRS Phoenix) are indicated to stabilize one or more pelvic bone fractures in the pelvis in an adult patient.

Indications for use of the I.T.S. Pelvic Reconstruction System (PRS RX) include:
• Fractures of the acetabulum
• Fractures of the pelvic ring
• Fractures of the quadrilateral surface
• Fractures of the sympyhsis
• Fractures of the ilium
• Fractures of the SIJ
• Ilio-iliac distance osteosynthesis
• Symphysis pubis disruptions, osteotomies, arthrodesis and sacroiliac joint dislocations
• Revision surgery of pseudoarthroses, non-unions and mal-unions
The I.T.S. PRS RX System is not intended for spinal use.

Indications for use of the I.T.S. Pelvic Reconstruction 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-symphyseal 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. PRS Phoenix System is not intended for spinal use.

Indications for use of the I.T.S. Infra-acetabular screw placement include:
• Fractures involving the anterior column, e.g. anterior column, anterior column plus posterior hemitransverse (ACPH) and associated both column (ABC) fractures
The I.T.S. Infra-acetabular screw is not intended for spinal use.

Indications for use of the I.T.S. 8.5mm Cannulated Screws & Washer include:
• Pelvic fractures
The I.T.S. 8.5mm Cannulated Screws & Washer are not intended for spinal use.

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.

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510(k) Summary of Safety and Effectiveness

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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510(k) FIRM CONTACT: Jennifer Hadfield
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TRADE NAME: **I.T.S. Pelvic Reconstruction System (PRS RX & PRS Phoenix)**

DATE: August 30th, 2022

COMMON NAME: Plate, Fixation, Bone; Screw, Fixation, Bone; Washer, Bolt Nut

CLASSIFICATION: Single/multiple component metallic bone fixation appliances and accessories (primary)
Class II, (*see 21 CFR. Sec. 888.3030*)
Smooth or threaded metallic bone fixation fastener
Class II, (*see 21 CFR Sec. 888.3040*)

DEVICE PRODUCT CODE: **HRS, HWC, HTN**

SUBSTANTIAL EQUIVALENCE:

PRIMARY PREDICATE I.T.S. - Pelvic Reconstruction System - PRS **(K063166)**

ADDITIONAL PREDICATES
I.T.S. - FLS Extremity System **(K131722)**
Stryker – Trauma Pelvic Set (**K001614**)
Stryker – Pelvis II Implant System **(K131132)**
Synthes – 3.5mm Low Profile Pelvic Reconstruction Plate **(K031573)**
Synthes – 3.5mm Quadrilateral Surface Plates **(K093928)**
Acumed – Pelvic Bone Plate System (**K122538**)
Synthes – 3.5mm Spring Plate **(K061973)**

DEVICE DESCRIPTION: The I.T.S. Pelvic Reconstruction System (PRS RX & PRS Phoenix) encompasses a number of fracture fixation subsystems of multiple plate designs for fracture fixation and reconstruction of pelvic ring fractures in the pelvis.

The I.T.S. Pelvic Reconstruction Plating System (PRS RX & PRS Phoenix) consists of the following plate types:

1) A Curved Plate at a 2.5mm thickness with 4 to 16 hole length sizes,
2) A Straight Plate at a 2.5mm thickness with 10 to 14 hole length sizes,
3) A SIJ Closed Plate at a 2.5mm thickness in a 4-hole size,
4) A SIJ L-Plate at a 2.5mm thickness in a 5-hole size,
5) A J-Plate at a 2.5mm thickness with 6 to 16 hole length sizes,

6) A Symphysis Plate at a 4.0mm thickness in a 4 & 6 hole size,
7) A Symphysis Plate Curved at a 4.0mm thickness in a 6 & 8 hole size,
8) A RIM Plate at a 2.5mm thickness in a 10 & 14 hole, Right & Left size,
9) A Posterior Wall Plate at a 2.5mm thickness in a 6 hole, Right & Left size,
10) A Posterior Wall Plate II at a 2.5mm thickness in a 7 & 8 hole, Right & Left size, ,
11) A Quadrilateral Column Plate at a 2.5mm thickness in a Small & Large, Right & Left size,
12) A Quadrilateral Supporting Plate at a 2.5mm thickness in a Right & Left size,
13) A Posterior Wall Plate Extended at a 2.5mm thickness in a Small & Large, Right & Left size,
14) A Posterior Column Plate at a 2.5mm thickness in a 8-hole, Right & Left size,

All plate designs are low profile in thickness and made from Implant Grade 2 CP Titanium material (to ASTM F67). The PRS RX & PRS Phoenix Plating System encompasses a 3.5mm Cortical Locking and Standard Screw and a 4.2mm Cancellous Locking Screw in various lengths. All bone screws are pre-drilling and self-tapping in design and manufactured from Implant Grade 5 high strength 6-4 Alloyed Titanium (to ASTM F136). A threaded Spike allows inter-operative plate fixation to bone fragments. The Spike is also manufactured from Implant Grade 5 high strength 6-4 Alloyed Titanium material (to ASTM F136).
All components (plates, screws, spike) have a anodize 'DOTIZE' Type II surface treatment preparation.
Ancillary instrumentation (Drills, Drill Guides, Insertion Guides, Clamps, Bending Heaver, Measuring Gauges, and Screwdrivers) is made available for bone fragment reduction and plate/screw placement and insertion. All plates, screws, spike are provided **Non-Sterile** for **single-use.**

INTENDED USE:

The I.T.S. Pelvic Reconstruction Systems (PRS RX & PRS Phoenix) are indicated to stabilize one or more pelvic bone fractures in the pelvis in an adult patient.
Indications for use of the I.T.S. Pelvic Reconstruction System (PRS RX) include:

- Fractures of the acetabulum,
- Fractures of the pelvic ring,
- Fractures of the quadrilateral surface,
- Fractures of the symphysis,
- Fractures of the ilium,
- Fractures of the SIJ,
- Ilio-iliac distance osteosynthesis,
- Symphysis pubis disruptures, osteotomies, arthrodesis and sacroiliac joint dislocations,
- Revision surgery of pseudoarthrosis, non-unions and mal-unions

The I.T.S. Pelvic Reconstruction System (PRS RX) is not intended for spinal use.

Indications for use of the I.T.S. Pelvic Reconstruction 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-symphyseal 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. Pelvic Reconstruction System (PRS Phoenix) is not intended for spinal use.

Indications for use of the I.T.S. Infra-acetabular screw placement include:

- Fractures involving the anterior column, e.g. anterior column, anterior column plus posterior hemitransverse (ACPH) and associated both column (ABC) fractures

The I.T.S. Infra-acetabular screw placement is not intended for spinal use.

Indications for use of the I.T.S. 8.5mm Cannulated Screws & Washer include:

- Pelvic fractures

The I.T.S. 8.5mm Cannulated Screws & Washer are not intended for spinal use.

BASIS OF SUBSTANTIAL EQIVLAENCE:

The I.T.S. Pelvic Reconstruction System (PRS RX & PRS Phoenix) is Substantially Equivalent (SE) to the I.T.S, Stryker, Synthes, and Acumed - Pelvic Reconstruction - Predicate Systems. An ***Engineering Analysis*** and ***Perfomance Testing*** was provided for **plate** bending strength and bending stiffness and **screw** insertion/removal, yield torque, self-tapping torque and axial pullout strength to demonstrate substantial equivalence. *Biocompatibility Risk Assessments* were also performed.

CLINICAL TESTING:

Clinical data was not submitted.

NON-CLINICAL TESTING:

Performance testing as a consensus standard was performed under ASTM F543 for all bone screws and under ASTM F382 for bone plates and in addition a FEA analysis simulation following ASTM F382.

SUMMARY OF TECHNO-LOGICAL CHARACTERISTICS:

The I.T.S. Pelvic Reconstruction System (PRS RX & PRS Phoenix) is **substantially equivalent** in material, geometry, design, indications and operational principles to the following predicate systems legally marketed in the US:

PRIMARY PREDICATE

I.T.S. - Pelvic Reconstruction System - PRS **(K063166)**

Differences in technological characteristics:

- Geometry / Dimensions / Design: comparable in plate sizes, thickness, width and locking features
- Material: identical CP titanium grade 2 for all plate components and identical titanium alloy 6Al-4V for all screw components
- Chemical composition: identical CP titanium grade 2 acc. to ASTM F67 and identical titanium alloy 6Al-4V acc. to ASTM F136
- Manufacturing: identical manufacturing steps
- Surface treatment: identical anodization with Type II

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. Pelvic Reconstruction System (PRS RX & PRS Phoenix) has been demonstrated to be **substantially equivalent** (SE) to the predicate devices.