

K210935 I.T.S. Pelvic Reconstruction System (PRS RX & PRS Phoenix)Aug 31, 2022
520 days to decisionK210935 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k210935/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Mar 29, 2021
Decision date	Aug 31, 2022
Days to decision	520 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	I.T.S. GmbH
Location	Prior Lake, MN, US
Contact	Florian Grill
510(k) history	7 submissions · 7 cleared · 2013-2026

REGULATORY CONSULTANT

Consulting firm	Qserve Group, Us, Inc.
Contact	Jennifer Hadfield

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210935/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026