FDA 510(k) Premarket Notification

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

CLEARED

Aug 31, 2022
520 days to decision

K210935 · 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