

K260054 I.T.S. PRS Phoenix IIApr 24, 2026
106 days to decisionK260054 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k260054/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jan 8, 2026
Decision date	Apr 24, 2026
Days to decision	106 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
Contact	Mindy Mccann

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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