

K250315 RONAVIS – FX (FX-001)Aug 1, 2025
178 days to decisionK250315 · Product code: HTY · Orthopedic
Source: <https://www.510kdatabase.net/k250315/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pin, Fixation, Smooth (HTY)
Date received	Feb 4, 2025
Decision date	Aug 1, 2025
Days to decision	178 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	AIRS, Inc.
Location	Daegu, KR
Contact	Sanghyun Joung
510(k) history	1 submissions · 1 cleared · 2025-2025

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