

**K252356 The Acumed Wrist Fixation System - 2.4mm Screws**Aug 21, 2025  
23 days to decisionK252356 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k252356/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plate, Fixation, Bone (HRS)
Date received	Jul 29, 2025
Decision date	Aug 21, 2025
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Acumed, LLC</b>
Location	Hillsboro, OR, US
Contact	Marina Bull
Website	<a href="http://www.acumed.net">http://www.acumed.net</a>
510(k) history	38 submissions · 38 cleared · 2003-2025

Acumed, LLC is a privately owned medical device manufacturer based in Hillsboro, Oregon. Founded in 1988, the company designs, manufactures, and markets orthopedic implants and surgical devices for global markets. Acumed has received FDA 510(k) clearances from total submissions since 2003. The company specializes exclusively in Orthopedic devices, with a regulatory track record spanning over two decades. The latest clearance in 2025 reflects continued active development and market engagement. The company's cleared device portfolio includes wrist fixation systems, ankle sy...