

K251296 The Acumed Wrist Fixation SystemJun 18, 2025
54 days to decisionK251296 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k251296/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Plate, Fixation, Bone (HRS)
Date received	Apr 25, 2025
Decision date	Jun 18, 2025
Days to decision	54 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Acumed, LLC
Location	Hillsboro, OR, US
Contact	Marina Bull
Website	http://www.acumed.net
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...