FDA 510(k) Premarket Notification

CLEARED

K221333 Acumed Acutrak System- MR Conditional, Acumed Acturak 2 System- MR Conditional

Dec 29, 2022
234 days to decision

K221333 · Product code: **HWC** · Orthopedic
Source: https://www.510kdatabase.net/k221333/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	May 9, 2022
Decision date	Dec 29, 2022
Days to decision	234 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Acumed, LLC**
Location	Hillsboro, OR, US
Contact	Saleh Amirriyazi
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...