

K230744 Acumed Acutrak 3 Headless Compression Screw System

Jun 9, 2023
84 days to decisionK230744 · Product code: **HWC** · Orthopedic
Source: <https://www.510kdatabase.net/k230744/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Screw, Fixation, Bone (HWC)
Date received	Mar 17, 2023
Decision date	Jun 9, 2023
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Acumed, LLC
Location	Hillsboro, OR, US
Contact	Phillip Saddik
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...