FDA 510(k) Premarket Notification

K133469 ACUMED SUTURE ANCHOR SYSTEM

CLEARED

Mar 10, 2014
118 days to decision

K133469 · Product code: **MBI** · Orthopedic
Source: https://www.510kdatabase.net/k133469/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Nov 12, 2013
Decision date	Mar 10, 2014
Days to decision	118 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Acumed, LLC**
Location	Hillsboro, OR, US
Contact	LINO TSAI
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k133469/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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