

**K140925 ACUMED SUTURE ANCHOR SYSTEM**May 20, 2014  
39 days to decisionK140925 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k140925/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fastener, Fixation, Nondegradable, Soft Tissue (MBI)
Date received	Apr 11, 2014
Decision date	May 20, 2014
Days to decision	39 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Acumed, LLC</b>
Location	Hillsboro, OR, US
Contact	LINO TSAI
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...

---