

**K112111 ACU-SINCH REPAIR SYSTEM AND ACUMED SUTURE ANCHOR**Nov 14, 2011  
112 days to decisionK112111 · Product code: **HTN** · Orthopedic  
Source: <https://www.510kdatabase.net/k112111/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Washer, Bolt Nut (HTN)
Date received	Jul 25, 2011
Decision date	Nov 14, 2011
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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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...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k112111/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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