

K212990 Acumed Ankle Syndesmosis Repair SystemJan 7, 2022
109 days to decisionK212990 · Product code: **HTN** · Orthopedic
Source: <https://www.510kdatabase.net/k212990/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Washer, Bolt Nut (HTN) |
| Date received | Sep 20, 2021 |
| Decision date | Jan 7, 2022 |
| Days to decision | 109 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Acumed, LLC |
| Location | Hillsboro, OR, US |
| Contact | Janki Bhatt |
| 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...

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Device record: <https://www.510kdatabase.net/k212990/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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