

K143385 Acumed Ankle Plating SystemApr 6, 2015
131 days to decisionK143385 · Product code: **HRS** · Orthopedic
Source: <https://www.510kdatabase.net/k143385/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Plate, Fixation, Bone (HRS) |
| Date received | Nov 26, 2014 |
| Decision date | Apr 6, 2015 |
| Days to decision | 131 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Acumed, LLC |
| Location | Hillsboro, OR, US |
| Contact | Nathan Wolf |
| 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...
