

K173656 Arthrex FibuLock NailJul 26, 2018
239 days to decisionK173656 · Product code: **HSB** · Orthopedic
Source: <https://www.510kdatabase.net/k173656/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Rod, Fixation, Intramedullary And Accessories (HSB) |
| Date received | Nov 29, 2017 |
| Decision date | Jul 26, 2018 |
| Days to decision | 239 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Arthrex, Inc. |
| Location | Naples, FL, US |
| Contact | Rebecca R. Homan |
| Website | https://www.arthrex.com |
| 510(k) history | 346 submissions · 342 cleared · 1992-2026 |

Arthrex, Inc. is a medical device manufacturer based in Naples, US. The company specializes in surgical implants and instruments for orthopedic procedures. Arthrex has received FDA 510(k) clearances from total submissions since its first clearance in 1992. The company's portfolio is dominated by Orthopedic devices, which represent 89% of its regulatory submissions. Recent cleared devices include suture anchors, plating systems, nails, and specialized fixation devices for shoulder, ankle, and lower extremity procedures. The latest FDA 510(k) clearance was received in 2026,...

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