

**K213644 Arthrex Knotless Mini TightRopes**Dec 17, 2021  
29 days to decisionK213644 · Product code: **HTN** · Orthopedic  
Source: <https://www.510kdatabase.net/k213644/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Washer, Bolt Nut (HTN)             |
| Date received         | Nov 18, 2021                       |
| Decision date         | Dec 17, 2021                       |
| Days to decision      | 29 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Arthrex, Inc.</b>  |
| Location       | Naples, FL, US  |
| Contact        | Rebecca R Homan   |
| Website        | <a href="https://www.arthrex.com">https://www.arthrex.com</a> |
| 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k213644/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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