

K193575 Arthrex SutureTapeJul 24, 2020
214 days to decisionK193575 · Product code: **GAT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193575/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Suture, Nonabsorbable, Synthetic, Polyethylene (GAT) |
| Date received | Dec 23, 2019 |
| Decision date | Jul 24, 2020 |
| Days to decision | 214 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Arthrex, Inc. |
| Location | Naples, FL, US |
| Contact | Ivette Galmez |
| 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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