

K253145 Pre-Sutured TendonOct 22, 2025
27 days to decisionK253145 · Product code: **GAT** · Orthopedic
Source: <https://www.510kdatabase.net/k253145/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Suture, Nonabsorbable, Synthetic, Polyethylene (GAT) |
| Date received | Sep 25, 2025 |
| Decision date | Oct 22, 2025 |
| Days to decision | 27 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Rti Surgical, Inc. |
| Location | Alachua, FL, US |
| Contact | Ellen Rounds |
| 510(k) history | 7 submissions · 7 cleared · 2014-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253145/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026