

K230036 Pre-Sutured Tendon (4561SC / Single Strand)Jun 23, 2023
178 days to decisionK230036 · Product code: **GAT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230036/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Dec 27, 2022
Decision date	Jun 23, 2023
Days to decision	178 days
Third-party review	No
Summary / Statement	Summary
Other names	Pre-Sutured Tendon (4564SC / Quadruple Strand)

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230036/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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