

**K181633 MTF Pre-Sutured Tendon**Mar 15, 2019  
268 days to decisionK181633 · Product code: **GAT** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k181633/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Nonabsorbable, Synthetic, Polyethylene (GAT)
Date received	Jun 20, 2018
Decision date	Mar 15, 2019
Days to decision	268 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Musculoskeletal Transplant Foundation</b>
Location	Edison, NJ, US
Contact	Katrina Carroll
510(k) history	24 submissions · 24 cleared · 2004-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Musculoskeletal Clinical Reulatory Advisers, LLC</b>
Contact	Katrina Carroll

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181633/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 18, 2026