

K231277 TissueStatNov 9, 2023
190 days to decisionK231277 · Product code: **NBY** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k231277/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Suture, Surgical, Nonabsorbable, Expanded, Polytetrafluoroethylene (NBY)
Date received	May 3, 2023
Decision date	Nov 9, 2023
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Durastat, LLC
Location	Austin, TX, US
Contact	Adam Azzara
510(k) history	1 submissions · 1 cleared · 2023-2023

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