

K101197 PARIE TENE PROGRIP MESHMay 5, 2010
7 days to decisionK101197 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k101197/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Apr 28, 2010
Decision date	May 5, 2010
Days to decision	7 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sofradim Production
Location	Ayer, MA, US
Contact	SHARON ALEXANDER
510(k) history	41 submissions · 41 cleared · 1999-2025

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