

K033376 UGYTEX MESHJan 15, 2004
85 days to decisionK033376 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k033376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Oct 22, 2003
Decision date	Jan 15, 2004
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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