

K172395 Duatene bilayer meshFeb 1, 2018
177 days to decisionK172395 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k172395/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Aug 8, 2017
Decision date	Feb 1, 2018
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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