

K163212 Parietene DS Composite MeshJun 29, 2017
225 days to decisionK163212 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k163212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Nov 16, 2016
Decision date	Jun 29, 2017
Days to decision	225 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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