

K223218 Parietene Macroporous MeshDec 2, 2022
46 days to decisionK223218 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k223218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Oct 17, 2022
Decision date	Dec 2, 2022
Days to decision	46 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Covidien
Contact	Wing Ng

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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