

K250869 Parietene™ Macroporous Mesh (PPM5050)Apr 23, 2025
30 days to decisionK250869 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250869/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Mar 24, 2025
Decision date	Apr 23, 2025
Days to decision	30 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, LLC
Contact	Nancy Sauer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250869/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026