

K253125 Parietene™ Flat Sheet MeshOct 24, 2025
29 days to decisionK253125 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k253125/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Sep 25, 2025
Decision date	Oct 24, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic - Sofradim Production
Location	Tr?voux, FR
Contact	Paula Paz
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253125/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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