FDA 510(k) Premarket Notification

K250869 Parietene™ Macroporous Mesh (PPM5050)

CLEARED

Apr 23, 2025
30 days to decision

K250869 · Product code: **FTL** · General & Plastic Surgery
Source: 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