FDA 510(k) Premarket Notification

K223218 Parietene Macroporous Mesh

CLEARED

Dec 2, 2022
46 days to decision

K223218 · Product code: **FTL** · General & Plastic Surgery
Source: 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