FDA 510(k) Premarket Notification

K003990 SOFRADIM PARIETEX SURGICAL MESHES

CLEARED

Jan 24, 2001
29 days to decision

K003990 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k003990/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Dec 26, 2000
Decision date	Jan 24, 2001
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sofradim Production**
Location	Ayer, MA, US
Contact	MARY MCNAMARA-CULLINANE
510(k) history	42 submissions · 42 cleared · 1999-2026