

K003990 SOFRADIM PARIETEX SURGICAL MESHESJan 24, 2001
29 days to decisionK003990 · Product code: **FTL** · General & Plastic SurgerySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003990/> 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 June 29, 2026