

K110816 PARIETEX OPTIMIZED COMPOSITE MESH (PCO-OSX REFERENCES)Apr 19, 2011
26 days to decision

K110816 · Product code: FTL · General & Plastic Surgery

Source: <https://www.510kdatabase.net/k110816/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Mar 24, 2011
Decision date	Apr 19, 2011
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sofradim Production
Location	Ayer, MA, US
Contact	JAMES MCMAHON
510(k) history	41 submissions · 41 cleared · 1999-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110816/> 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 May 14, 2026