

K110663 PAIRETEX OPTIMIZED COMPOSITE MESH (PCO-FX REFERENCES)Aug 11, 2011
156 days to decision

K110663 · Product code: FTL · General & Plastic Surgery

Source: <https://www.510kdatabase.net/k110663/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Mar 8, 2011
Decision date	Aug 11, 2011
Days to decision	156 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

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