

**K173796 Parietex Surgical Mesh (modified into Parietex Hydrophilic 2D, 3D, Anatomical Mesh), Parietex Composite Mesh (PCO and PCO-OS references), Parietex Optimized Composite Mesh (PCO-X, PCO-FX and PCO-OSX references)**Mar 9, 2018  
85 days to decisionK173796 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k173796/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Dec 14, 2017
Decision date	Mar 9, 2018
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sofradim Production</b>
Location	Ayer, MA, US
Contact	Benjamin Rochette
510(k) history	41 submissions · 41 cleared · 1999-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173796/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026