

**K081126 PARIETEX COMPOSITE MONO PM MESH**Aug 13, 2008  
114 days to decisionK081126 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k081126/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Apr 21, 2008
Decision date	Aug 13, 2008
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Sofradim Production</b>
Location	Ayer, MA, US
Contact	SHARON ALEXANDER
510(k) history	42 submissions · 42 cleared · 1999-2026

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081126/> 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 June 24, 2026