

K232373 ProGrip™ Self-Gripping Polypropylene MeshJan 18, 2024
163 days to decisionK232373 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k232373/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Aug 8, 2023
Decision date	Jan 18, 2024
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	Covidien, LLC
Contact	Nancy Sauer

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)**510k Database** - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232373/> 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