FDA 510(k) Premarket Notification

K232373 Progrip™ Self-Gripping Polypropylene Mesh

CLEARED

Jan 18, 2024
163 days to decision

K232373 · Product code: **FTL** · General & Plastic Surgery
Source: 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