FDA 510(k) Premarket Notification

K142091 PARIETENE MACROPOROUS MESH

CLEARED

Oct 17, 2014
77 days to decision

K142091 · Product code: **FTL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k142091/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Aug 1, 2014
Decision date	Oct 17, 2014
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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