FDA 510(k) Premarket Notification

K233999 GalaFLEX LITE Scaffold

CLEARED

Apr 9, 2024
113 days to decision

K233999 · Product code: **OOD** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233999/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Surgical Film (OOD)
Date received	Dec 18, 2023
Decision date	Apr 9, 2024
Days to decision	113 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Tepha, Inc.**
Location	Cambridge, MA, US
Contact	Rajagopalan Prithi
510(k) history	18 submissions · 17 cleared · 2007-2024