FDA 510(k) Premarket Notification

K243302 3DMatrix DynaFlex (DynaFlex)

CLEARED

May 21, 2025
215 days to decision

K243302 · Product code: **OXF** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k243302/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Mesh, Surgical, Absorbable, Plastic And Reconstructive Surgery (OXF)
Date received	Oct 18, 2024
Decision date	May 21, 2025
Days to decision	215 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Printbio, Inc.**
Location	Long Island City, NY, US
Contact	Janet Vargo
510(k) history	2 submissions · 2 cleared · 2024-2025