

K243302 3DMatrix DynaFlex (DynaFlex)May 21, 2025
215 days to decisionK243302 · Product code: **OXF** · General & Plastic SurgerySource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243302/> 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 13, 2026