

K233368 Allograft Delivery Device (OFAC-C)Jun 25, 2024
267 days to decisionK233368 · Product code: **FMF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233368/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Oct 2, 2023
Decision date	Jun 25, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bioventus, LLC
Location	Durham, NC, US
Contact	Shanna Hu
510(k) history	5 submissions · 5 cleared · 2017-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233368/> 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 14, 2026