FDA 510(k) Premarket Notification

K233368 Allograft Delivery Device (OFAC-C)

CLEARED

Jun 25, 2024
267 days to decision

K233368 · Product code: **FMF** · General & Plastic Surgery
Source: 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