FDA 510(k) Premarket Notification

CLEARED

K261335 VitalFlow Set with Balance™ Biosurface

Jul 31, 2026
99 days to decision

K261335 · Product code: **QJZ** · Cardiovascular
Source: https://www.510kdatabase.net/k261335/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Extracorporeal System For Long-term Respiratory / Cardiopulmonary Failure (QJZ)
Date received	Apr 23, 2026
Decision date	Jul 31, 2026
Days to decision	99 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	Vinoda Palanisamy
Website	https://www.medtronic.com
510(k) history	211 submissions · 210 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...