

K223168 Tubing and Accessories Sets for Extracorporeal Membrane Oxygenation (ECMO) with Balance™ Biosurface

Apr 19, 2023
190 days to decisionK223168 · Product code: QWF · Cardiovascular
Source: <https://www.510kdatabase.net/k223168/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubing, Long Term Support Greater Than 6 Hours (QWF)
Date received	Oct 11, 2022
Decision date	Apr 19, 2023
Days to decision	190 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	Anna Wetherille
Website	https://www.medtronic.com
510(k) history	209 submissions · 208 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,...