

# K201068 Affinity CP Centrifugal Blood Pump, Affinity CP Centrifugal Blood Pump with Balance Biosurface, Affinity CP Centrifugal Blood Pump with Cortiva BioActive Surface

May 21, 2020  
29 days to decision

K201068 · Product code: **KFM** · Cardiovascular  
Source: <https://www.510kdatabase.net/k201068/>

## SUBMISSION DETAILS

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Apr 22, 2020
Decision date	May 21, 2020
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

## APPLICANT

---

Company	<b>Medtronic, Inc.</b>
Location	Mounds View, MN, US
Contact	Sammie C. Joseph-Fredericks
Website	<a href="https://www.medtronic.com">https://www.medtronic.com</a>
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,...