CLEARED

Aug 27, 2019
126 days to decision

K191077 Affinity CP Centrifugal Blood Pump, Affinity CP Centrifugal Blood Pump with Balance Biosurface, Affinity CP Centrifugal Blood Pump with Cortive BioActive Surface, Medtronic External Drive Motor

K191077 · Product code: **KFM** · Cardiovascular
Source: https://www.510kdatabase.net/k191077/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Blood, Cardiopulmonary Bypass, Non-roller Type (KFM)
Date received	Apr 23, 2019
Decision date	Aug 27, 2019
Days to decision	126 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	Harsh Dharamshi
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,...