CLEARED

Apr 12, 2019
116 days to decision

K183490 Affinity NT Oxygenator, Affinity NT Oxygenator with Trillium Biosurface, Affinity NT Oxygenator with Cortiva BioActive Surface, Affinity Fusion Oxygenator with Cortiva BioActive Surface, Affinity Fusion Oxygenator with Balance Biosurface

K183490 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k183490/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Dec 17, 2018
Decision date	Apr 12, 2019
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	Wendy Pinor
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,...