CLEARED

May 17, 2019
29 days to decision

K191029 Affinity NTTM Oxygenator (Model 511), Affinity® NT Hollow Fiber Oxygenator with Plasma Resistant Fiber (PRF) with TrilliumTM Biosurface (Model 511T), Affinity® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber (Model 541), Affinity® NT Integrated CVR/Membrane Oxygenator with Plasma Resistant Fiber (Model 541-R), Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurface (Model 541T), Affinity NT® Integrated CVR/Membrane Oxygenator with Trillium® Biosurfac

K191029 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k191029/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Apr 18, 2019
Decision date	May 17, 2019
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	Sammie C Joseph-Fredericks
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,...