FDA 510(k) Premarket Notification

CLEARED

K241352 Affinity NT Oxygenator and Uncoated Cardiotomy/ Venous Reservoir (541)

Jun 12, 2024
30 days to decision

K241352 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k241352/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	May 13, 2024
Decision date	Jun 12, 2024
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Affinity NT Oxygenator with Balance Biosurface and Uncoated Cardiotomy/Venous Reservoir (541B)

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	Kaitlin Cady
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,...