CLEARED

Nov 20, 2017
54 days to decision

K172984 Affinity Pixie Oxygenator with Balance Biosurface, Affinity Pixie Oxygenator with Cardiotomy/Venous Reservoir and Balance Biosurface, Affinity Pixie Oxygenator with Cortiva BioActive Surface, Affinity Fusion Oxygenator with Cardiotomy/Venous Reservoir and Cortiva BioActive Surface

K172984 · Product code: **DTZ** · Cardiovascular
Source: https://www.510kdatabase.net/k172984/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Sep 27, 2017
Decision date	Nov 20, 2017
Days to decision	54 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	Lisa Stone
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,...