

K183511 Affinity Pixie™ Oxygenator with Balance™ Biosurface (Model BBP211), Affinity Pixie™ Oxygenator and Cardiotomy/Venous Reservoir with Balance™ Biosurface (Model BBP241), Affinity Pixie™ Oxygenator with Cortiva™ BioActive Surface (Model CBP211), Affinity Pixie™ Oxygenator and Cardiotomy/Venous Reservoir with Cortiva™ BioActive Surface (Model CBP241)

Mar 18, 2019
90 days to decision

K183511 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k183511/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Dec 18, 2018
Decision date	Mar 18, 2019
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	Tyler Senjem
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,...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k183511/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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