

K240666 Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface (BB811)Jul 10, 2024
124 days to decisionK240666 · Product code: DTZ · Cardiovascular
Source: <https://www.510kdatabase.net/k240666/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Mar 8, 2024
Decision date	Jul 10, 2024
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Affinity Fusion Oxygenator with Integrated Arterial Filter and Cardiotomy/Venous Reservoir with Balance Biosurface (BB841); Affinity Fusion Oxygenator with Integrated Arterial Filter and Balance Biosurface NON STERILE (BB811-NS)

APPLICANT

Company	Medtronic Perfusion Systems
Location	Minneapolis, MN, US
Contact	Megan Schlichting
510(k) history	29 submissions · 29 cleared · 2000-2024

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