

K203111 Affinity Fusion Oxygenator System, Affinity Pixie Oxygenation System

Sep 16, 2021
336 days to decisionK203111 · Product code: **DTZ** · Cardiovascular
Source: <https://www.510kdatabase.net/k203111/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oxygenator, Cardiopulmonary Bypass (DTZ)
Date received	Oct 15, 2020
Decision date	Sep 16, 2021
Days to decision	336 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic
Location	Minneapolis, MN, US
Contact	Kaitlin Cady
Website	http://www.medtronic.com/us-en/index.html
510(k) history	32 submissions · 32 cleared · 2007-2026

Medtronic is an American-Irish medical device company with operational headquarters in Minneapolis, Minnesota. The company operates globally across more than 150 countries and is the largest medical device company in the world by revenue. Medtronic has received FDA 510(k) clearances from total submissions since 2007. The company's regulatory portfolio is dominated by cardiovascular devices, including oxygenation systems, arterial filters, cardioplegia delivery systems, and catheter-based interventions. Medtronic also maintains a significant presence in orthopedic spinal s...