FDA 510(k) Premarket Notification

CLEARED

K240190 MYOtherm XP Cardioplegia Delivery System with Cortiva BioActive Surface, MYOtherm XP Cardioplegia Delivery System Uncoated

Feb 23, 2024
30 days to decision

K240190 · Product code: **DTR** · Cardiovascular
Source: https://www.510kdatabase.net/k240190/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Jan 24, 2024
Decision date	Feb 23, 2024
Days to decision	30 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...