

K162774 MYOtherm XP Cardioplegia Delivery System with Cortiva BioActive Surface, MYOtherm XP Cardioplegia Delivery System with Cortiva BioActive Surface (Bridge System)

Feb 10, 2017
130 days to decision

K162774 · Product code: DTR · Cardiovascular
Source: <https://www.510kdatabase.net/k162774/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Heat-exchanger, Cardiopulmonary Bypass (DTR)
Date received	Oct 3, 2016
Decision date	Feb 10, 2017
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	Harsh Dharamshi
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,...