FDA 510(k) Premarket Notification

**CLEARED**

# K162958 MYOtherm XP Cardioplegia Delivery System with Trillium Biosurface

Feb 1, 2017
100 days to decision

K162958 · Product code: **DTR** · Cardiovascular
Source: https://www.510kdatabase.net/k162958/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Heat-exchanger, Cardiopulmonary Bypass (DTR) |
| Date received | Oct 24, 2016 |
| Decision date | Feb 1, 2017 |
| Days to decision | 100 days |
| Third-party review | No |
| Summary / Statement | Summary |
| Other names | MYOtherm XP Cardioplegia Delivery System with Trillium Biosurface with Bridge; MYOtherm XP Cardioplegia Delivery System; MYOtherm XP Cardioplegia Delivery System with Bridge |

## 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,...