FDA 510(k) Premarket Notification

K070286 BIO-CONSOLE, MODEL 560

CLEARED

May 22, 2007
113 days to decision

K070286 · Product code: **DWA** · Cardiovascular
Source: https://www.510kdatabase.net/k070286/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Control, Pump Speed, Cardiopulmonary Bypass (DWA)
Date received	Jan 29, 2007
Decision date	May 22, 2007
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic**
Location	Minneapolis, MN, US
Contact	CHERYL NORTON
Website	http://www.medtronic.com/us-en/index.html
510(k) history	33 submissions · 33 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...