FDA 510(k) Premarket Notification

K102953 HEPARIN DOSE RESPONSE CARTRIDGE

CLEARED

Nov 4, 2010
31 days to decision

K102953 · Product code: **JOX** · Hematology
Source: https://www.510kdatabase.net/k102953/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Analyzer, Heparin, Automated (JOX)
Date received	Oct 4, 2010
Decision date	Nov 4, 2010
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	JEFFERY L KOLL
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,...