FDA 510(k) Premarket Notification

K103313 HEPARIN ASSAY CONTROLS

CLEARED

Dec 1, 2010
21 days to decision

K103313 · Product code: **GGN** · Hematology
Source: https://www.510kdatabase.net/k103313/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Plasma, Coagulation Control (GGN)
Date received	Nov 10, 2010
Decision date	Dec 1, 2010
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	JEFFREY 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,...