FDA 510(k) Premarket Notification

CLEARED

K201118 Exacta External Drainage and Monitoring System, Exacta Pole with Laser Level, Exacta System Replacement Drainage Bag, Replacement Laser Level

May 26, 2020
29 days to decision

K201118 · Product code: **GWM** · Neurology
Source: https://www.510kdatabase.net/k201118/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Monitoring, Intracranial Pressure (GWM)
Date received	Apr 27, 2020
Decision date	May 26, 2020
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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