FDA 510(k) Premarket Notification

K132673 5F & 6F LAUNCHER GUIDE CATHETER, 5F SHERPA ACTIVE NX GUIDE CATHETER, 6F Z4 GUIDING CATHETER

CLEARED

Oct 22, 2013
56 days to decision

K132673 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k132673/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Percutaneous (DQY)
Date received	Aug 27, 2013
Decision date	Oct 22, 2013
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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