

K081804 PIONEER PLUS CATHETERAug 5, 2008
40 days to decisionK081804 · Product code: **PDU** · Cardiovascular
Source: <https://www.510kdatabase.net/k081804/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Jun 26, 2008
Decision date	Aug 5, 2008
Days to decision	40 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic, Inc.
Location	Mounds View, MN, US
Contact	CATHERINE PRIESTLEY
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,...

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081804/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 24, 2026