

**K072155 PIONEER CATHETER**Oct 5, 2007  
63 days to decisionK072155 · Product code: **PDU** · Radiology  
Source: <https://www.510kdatabase.net/k072155/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter For Crossing Total Occlusions (PDU)
Date received	Aug 3, 2007
Decision date	Oct 5, 2007
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medtronic, Inc.</b>
Location	Mounds View, MN, US
Contact	CATHERINE PRIESTLEY
Website	<a href="https://www.medtronic.com">https://www.medtronic.com</a>
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,...

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