

K012083 ATTAIN ACCESS 6218 LEFT-HEART DELIVERY SYSTEM, MODEL 6218Aug 28, 2001
56 days to decisionK012083 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k012083/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Jul 3, 2001
Decision date	Aug 28, 2001
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medtronic Vascular
Location	Walker, MI, US
Contact	KAREN REIDT
510(k) history	475 submissions · 453 cleared · 1977-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k012083/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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