

K912191 SOFTOUCH(R) GUIDING CATHETER W/BUMPER TIPJul 30, 1991
74 days to decisionK912191 · Product code: **DQY** · CardiovascularSource: <https://www.510kdatabase.net/k912191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	May 17, 1991
Decision date	Jul 30, 1991
Days to decision	74 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Mallinckrodt Medical
Location	St Louis, MO, US
Contact	DAVID E BROWN
510(k) history	43 submissions · 42 cleared · 1990-2008

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912191/> 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 May 20, 2026