

**K002676 ENDOVANCE DUALPASS TEAR-AWAY SHEATH
INTRODUCER**Oct 30, 2000
63 days to decisionK002676 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k002676/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 28, 2000
Decision date	Oct 30, 2000
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Guidant Cardiac and Vascular Surgery
Location	Menlo Park, CA, US
Contact	KRISTEN HONL
510(k) history	7 submissions · 7 cleared · 1997-2002

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002676/> 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