FDA 510(k) Premarket Notification

K002676 ENDOVANCE DUALPASS TEAR-AWAY SHEATH INTRODUCER

CLEARED

Oct 30, 2000
63 days to decision

K002676 · 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