

**K112407 SMITH MEDICAL PEEL-AWAY SHEATH  
INTRODUCERS**Feb 9, 2012  
171 days to decisionK112407 · Product code: **DYB** · Cardiovascular  
Source: <https://www.510kdatabase.net/k112407/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 22, 2011
Decision date	Feb 9, 2012
Days to decision	171 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Smiths Medical MD, Inc.</b>
Location	St. Paul, MN, US
Contact	TOM BLISS
510(k) history	20 submissions · 20 cleared · 2004-2012

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112407/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 15, 2026