

K131144 AMECO SHEATH INTRODUCERAug 15, 2013
114 days to decisionK131144 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k131144/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Apr 23, 2013
Decision date	Aug 15, 2013
Days to decision	114 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Ameco Medical Industries
Location	Mason, NH, US
Contact	RAYMOND J KELLY
510(k) history	6 submissions · 5 cleared · 2011-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k131144/> 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 June 3, 2026