

K102008 GLIDESHEATHJul 21, 2010
5 days to decisionK102008 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k102008/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Jul 16, 2010
Decision date	Jul 21, 2010
Days to decision	5 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Terumo Medical Corp.
Location	Elkton, MD, US
Contact	DANIEL R PLONSKI
510(k) history	143 submissions · 143 cleared · 1980-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k102008/> 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 27, 2026