

K033681 GLIDESHEATHDec 11, 2003
17 days to decisionK033681 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k033681/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Nov 24, 2003
Decision date	Dec 11, 2003
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Corp.
Location	Somerset, NJ, US
Contact	MARK UNTERREINER
510(k) history	21 submissions · 21 cleared · 1991-2010

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033681/> 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 21, 2026