

K070816 PERIPHERAL GUIDING SHEATHSep 19, 2007
177 days to decisionK070816 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k070816/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Mar 26, 2007
Decision date	Sep 19, 2007
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Micrus Design Technology, Inc.
Location	Miami, FL, US
Contact	MARIANNE GRUNWALDT, MS, CQE
510(k) history	1 submissions · 1 cleared · 2007-2007

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k070816/> 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 26, 2026