FDA 510(k) Premarket Notification

K070816 PERIPHERAL GUIDING SHEATH

CLEARED

Sep 19, 2007
177 days to decision

K070816 · 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