

K012854 RENAL GUIDING SHEATHNov 21, 2001
89 days to decisionK012854 · Product code: **DYB** · CardiovascularSource: <https://www.510kdatabase.net/k012854/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Aug 24, 2001
Decision date	Nov 21, 2001
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Medical Corp.
Location	Elkton, MD, US
Contact	YUK-TING LEWIS
510(k) history	143 submissions · 143 cleared · 1980-2011

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