

**K001139 PREFACE GUIDING SHEATH, MODELS 2-603M,
2-703M, 2-803M, 2-903M, 2-1003M, 2-1103M**May 10, 2000
30 days to decisionK001139 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k001139/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Apr 10, 2000
Decision date	May 10, 2000
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biosense Webster, Inc.
Location	Irvine, CA, US
Contact	MARY ADAMS
Website	https://www.jnjmedtech.com
510(k) history	73 submissions · 73 cleared · 1999-2026

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