FDA 510(k) Premarket Notification

K013919 TORFLEX TRANSSEPTAL GUIDING SHEATH

CLEARED

Feb 22, 2002
87 days to decision

K013919 · Product code: **DBY** · Immunology
Source: https://www.510kdatabase.net/k013919/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fab, Rhodamine, Antigen, Antiserum, Control (DBY)
Date received	Nov 27, 2001
Decision date	Feb 22, 2002
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Baylis Medical Co., Inc.**
Location	Mississauga, CA
Contact	KRIS SHAH
510(k) history	28 submissions · 28 cleared · 1998-2013

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k013919/ 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 May 19, 2026