

K993376 ENSTYLET MODELS EC0010, EC0020Jan 5, 2000
90 days to decisionK993376 · Product code: **DRB** · Cardiovascular
Source: <https://www.510kdatabase.net/k993376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stylet, Catheter (DRB)
Date received	Oct 7, 1999
Decision date	Jan 5, 2000
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Endocardial Solutions, Inc.
Location	St. Paul, MN, US
Contact	JAMES BULLOCK
510(k) history	8 submissions · 4 cleared · 1999-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k993376/> 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 July 3, 2026