

K011727 TRANSSEPTAL NEEDLE/TROCARMay 2, 2002
332 days to decisionK011727 · Product code: **DRC** · CardiovascularSource: <https://www.510kdatabase.net/k011727/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Trocar (DRC)
Date received	Jun 4, 2001
Decision date	May 2, 2002
Days to decision	332 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Thomas Medical Products, Inc.
Location	Malvern, PA, US
Contact	TIM STOUDT
510(k) history	23 submissions · 23 cleared · 1990-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011727/> 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 June 9, 2026