FDA 510(k) Premarket Notification

K011727 TRANSSEPTAL NEEDLE/TROCAR

CLEARED

May 2, 2002
332 days to decision

K011727 · Product code: **DRC** · Cardiovascular
Source: 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