FDA 510(k) Premarket Notification

K081341 REINFORCED CATHETER INTRODUCER SYSTEM (RCIS)

CLEARED

May 14, 2008
1 days to decision

K081341 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k081341/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	May 13, 2008
Decision date	May 14, 2008
Days to decision	1 days
Third-party review	Yes
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