FDA 510(k) Premarket Notification

K040713 MODIFICATION TO BRAIDED GUIDING INTRODUCER SYSTEM

CLEARED

Jun 1, 2004
75 days to decision

K040713 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k040713/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Introducer, Catheter (DYB)
Date received	Mar 18, 2004
Decision date	Jun 1, 2004
Days to decision	75 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