FDA 510(k) Premarket Notification

K092372 HEARTRAIL III GUIDING CATHETER

CLEARED

Sep 11, 2009
37 days to decision

K092372 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k092372/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Aug 5, 2009
Decision date	Sep 11, 2009
Days to decision	37 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Terumo Corp.**
Location	Somerset, NJ, US
Contact	MARK UNTERREINER
510(k) history	21 submissions · 21 cleared · 1991-2010