FDA 510(k) Premarket Notification

K090040 RADIFOCUS GLIDECATH (OR RADIFOCUS GLIDECATH XP)

CLEARED

Feb 6, 2009
31 days to decision

K090040 · Product code: **DQO** · Cardiovascular
Source: https://www.510kdatabase.net/k090040/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Diagnostic (DQO)
Date received	Jan 6, 2009
Decision date	Feb 6, 2009
Days to decision	31 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Terumo Medical Corp.**
Location	Elkton, MD, US
Contact	MARK UNTERREINER
510(k) history	143 submissions · 143 cleared · 1980-2011