

K953533 RADIFOCUS GLIDEWIRE FOR CORONARY USE WITH PLATINUM (OR GOLD) COIL

Oct 18, 1995
83 days to decision

K953533 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k953533/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Jul 27, 1995
Decision date	Oct 18, 1995
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Medical Corp.
Location	Elkton, MD, US
Contact	KEITH M SMITH
510(k) history	143 submissions · 143 cleared · 1980-2011

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k953533/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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