FDA 510(k) Premarket Notification

K240818 R2P Radifocus Glidewire Advantage

CLEARED

Nov 26, 2024
246 days to decision

K240818 · Product code: **DQX** · Cardiovascular
Source: https://www.510kdatabase.net/k240818/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Wire, Guide, Catheter (DQX)
Date received	Mar 25, 2024
Decision date	Nov 26, 2024
Days to decision	246 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Corporation**
Location	Shibuya-Ku, Tokyo, JP
Contact	Qing Liu
510(k) history	13 submissions · 13 cleared · 2012-2026

REGULATORY CONSULTANT

Consulting firm	**Terumo Medical Corporation**
Contact	Qing Liu

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov