FDA 510(k) Premarket Notification

K220934 RADIFOCUS Torque Device

CLEARED

Jun 29, 2022
90 days to decision

K220934 · Product code: **MOF** · Neurology
Source: https://www.510kdatabase.net/k220934/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Wire, Catheter, Neurovasculature (MOF)
Date received	Mar 31, 2022
Decision date	Jun 29, 2022
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Medical Products Hangzhou Co., Ltd.**
Location	Elkton, MD, US
Contact	Qing Liu
510(k) history	5 submissions · 5 cleared · 2003-2025

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