

**K220934 RADIFOCUS Torque Device**Jun 29, 2022  
90 days to decisionK220934 · Product code: **MOF** · Neurology  
Source: <https://www.510kdatabase.net/k220934/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Terumo Medical Corporation</b>
Contact	Qing Liu

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

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