

**K093397 TRAXCESS 14EX GUIDEWIRE AND TRAXCESS DOCKING WIRE**Dec 17, 2009  
48 days to decisionK093397 · Product code: **DQX** · Cardiovascular  
Source: <https://www.510kdatabase.net/k093397/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Wire, Guide, Catheter (DQX)
Date received	Oct 30, 2009
Decision date	Dec 17, 2009
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>MicroVention, Inc.</b>
Location	Aliso Viejo, CA, US
Contact	Naomi Gong
Website	<a href="https://www.microvention.com">https://www.microvention.com</a>
510(k) history	85 submissions · 85 cleared · 2001-2024

MicroVention, Inc., now operating as Terumo Neuro, is a neuroendovascular medical device company headquartered in Aliso Viejo, California. The company develops and commercializes catheter-based, minimally invasive technologies for treating neurovascular disorders including hemorrhagic stroke, ischemic stroke, carotid artery disease, and neurovascular malformations. MicroVention has maintained a strong FDA 510(k) regulatory record since its first clearance in 2001. The company has received FDA 510(k) clearances from total submissions, with no denied submissions. The latest...