

K200547 Traxcess 14 SELECT GuidewireApr 16, 2020
44 days to decisionK200547 · Product code: **MOF** · Neurology
Source: <https://www.510kdatabase.net/k200547/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Guide, Wire, Catheter, Neurovasculature (MOF)
Date received	Mar 3, 2020
Decision date	Apr 16, 2020
Days to decision	44 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	MicroVention, Inc.
Location	Aliso Viejo, CA, US
Contact	Ganesh Balachandar
Website	https://www.microvention.com
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...

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Device record: <https://www.510kdatabase.net/k200547/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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