

K083343 HEADWAY 17 MICROCATHETERDec 4, 2008
21 days to decisionK083343 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k083343/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Nov 13, 2008
Decision date	Dec 4, 2008
Days to decision	21 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	MicroVention, Inc.
Location	Aliso Viejo, CA, US
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/k083343/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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