

**K100454 HYDROCOIL EMBOLIC SYSTEM-HYDROFRAME
MODEL 100931HFM-V, 101243HFM-V, 180827HFM-V,
181139HFM-V, 181445HFM-V, 181850HFM-V**Apr 22, 2010
64 days to decisionK100454 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k100454/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Feb 17, 2010
Decision date	Apr 22, 2010
Days to decision	64 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	MicroVention, Inc.
Location	Aliso Viejo, CA, US
Contact	LARAINÉ PANGELINA
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...