

**K103758 MICROPLEX COIL SYSTEM- COSMOS 10, HYDROCOIL SYSTEM- HYDROFRAME 10**Apr 28, 2011  
126 days to decisionK103758 · Product code: **HCG** · Neurology  
Source: <https://www.510kdatabase.net/k103758/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Dec 23, 2010
Decision date	Apr 28, 2011
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>MicroVention, Inc.</b>
Location	Aliso Viejo, CA, US
Contact	LARAIN PANGELINA
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...

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Device record: <https://www.510kdatabase.net/k103758/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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