

**K093002 AZUR PERIPHERAL HYDROCOIL ENDOVASCULAR  
EMBOLIZATION SYSTEM-DETACHABLE 35, MODELS  
45-450405, 45-450410, 45-450610**Oct 28, 2009  
30 days to decisionK093002 · Product code: **KRD** · Cardiovascular  
Source: <https://www.510kdatabase.net/k093002/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Sep 28, 2009
Decision date	Oct 28, 2009
Days to decision	30 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...