

K050954 MICROPLEX COIL SYSTEM (MCS) AND HYDROCOIL EMBOLIC SYSTEM (HES)Jun 28, 2005
74 days to decisionK050954 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k050954/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Neurovascular Embolization (HCG) |
| Date received | Apr 15, 2005 |
| Decision date | Jun 28, 2005 |
| Days to decision | 74 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | MicroVention, Inc. |
| Location | Aliso Viejo, CA, US |
| Contact | VINCENT CUTARELLI |
| 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/k050954/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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