

K071939 HYDROCOIL EMBOLIC SYSTEMS (HES)Jan 11, 2008
182 days to decisionK071939 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k071939/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Vascular, For Promoting Embolization (KRD) |
| Date received | Jul 13, 2007 |
| Decision date | Jan 11, 2008 |
| Days to decision | 182 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...
