FDA 510(k) Premarket Notification

# K132083 AZUR PURE PERIPHERAL COIL SYSTEMS, PUSHABLE 35

**CLEARED**

Oct 28, 2013
115 days to decision

K132083 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k132083/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Vascular, For Promoting Embolization (KRD) |
| Date received | Jul 5, 2013 |
| Decision date | Oct 28, 2013 |
| Days to decision | 115 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **MicroVention, Inc.** |
| Location | Aliso Viejo, CA, US |
| Contact | LARAINE PANGELINA |
| 510(k) history | 85 submissions · 85 cleared · 2001-2024 |