

K191680 AZUR Vascular PlugMar 20, 2020
270 days to decisionK191680 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k191680/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Jun 24, 2019
Decision date	Mar 20, 2020
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	MicroVention, Inc.
Location	Aliso Viejo, CA, US
Contact	Ganesh Balachander
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...