FDA 510(k) Premarket Notification

K162524 AZUR CX Detachable 18 Peripheral Coil System

CLEARED

Mar 3, 2017
175 days to decision

K162524 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k162524/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Sep 9, 2016
Decision date	Mar 3, 2017
Days to decision	175 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