FDA 510(k) Premarket Notification

K202850 Concerto Versa, Detachable Coil

CLEARED

Feb 9, 2021
134 days to decision

K202850 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k202850/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Sep 28, 2020
Decision date	Feb 9, 2021
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Micro Therapeutics, Inc. d/b/a ev3 Neurovascular**
Location	Lrvine, CA, US
Contact	Rita De Rama
510(k) history	32 submissions · 32 cleared · 2014-2025