

K202850 Concerto Versa, Detachable CoilFeb 9, 2021
134 days to decisionK202850 · Product code: **KRD** · CardiovascularSource: <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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202850/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026