FDA 510(k) Premarket Notification

CLEARED

K261866 Concerto Versa™ Detachable Coil

Jun 24, 2026
20 days to decision

K261866 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k261866/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	Jun 4, 2026
Decision date	Jun 24, 2026
Days to decision	20 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic, Inc.**
Location	Mounds View, MN, US
Contact	Rishu Rathee
Website	https://www.medtronic.com
510(k) history	210 submissions · 209 cleared · 1981-2026

Medtronic, Inc. is a global medical device manufacturer headquartered in Mounds View, United States. The company develops and markets a broad range of medical devices across multiple therapeutic areas. Medtronic maintains a strong FDA 510(k) regulatory track record with FDA 510(k) cleared devices from total submissions since 1981. The company specializes primarily in Cardiovascular devices, which represent 82% of its submission portfolio. Recent clearances include coronary perfusion cannulae, intracoronary shunts, venous cannulae, guidewires, deflectable catheter systems,...