

K251383 Prestige Coil System (Prestige Packing Line Extension)May 30, 2025
28 days to decisionK251383 · Product code: **KRD** · Cardiovascular
Source: <https://www.510kdatabase.net/k251383/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Vascular, For Promoting Embolization (KRD)
Date received	May 2, 2025
Decision date	May 30, 2025
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Balt USA, LLC
Location	Irvine, CA, US
Contact	Kavita Chandrashekar
510(k) history	18 submissions · 18 cleared · 2018-2026

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