

K242582 Optima Coil System (OptiBlock Line Extension)Sep 27, 2024
28 days to decisionK242582 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k242582/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Aug 30, 2024
Decision date	Sep 27, 2024
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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k242582/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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