

K223386 Optima Coil SystemDec 6, 2022
29 days to decisionK223386 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k223386/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Nov 7, 2022
Decision date	Dec 6, 2022
Days to decision	29 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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