

K200030 Optima Coil SystemFeb 1, 2020
25 days to decisionK200030 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k200030/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Jan 7, 2020
Decision date	Feb 1, 2020
Days to decision	25 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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