

**K254221 Optima Coil System (OptiOne Coil System)**Jan 27, 2026  
29 days to decisionK254221 · Product code: **HCG** · Neurology  
Source: <https://www.510kdatabase.net/k254221/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Special                                  |
| Device classification | Device, Neurovascular Embolization (HCG) |
| Date received         | Dec 29, 2025                             |
| Decision date         | Jan 27, 2026                             |
| Days to decision      | 29 days                                  |
| Third-party review    | No                                       |
| Combination product   | No                                       |
| PCCP authorized       | No                                       |
| Summary / Statement   | Summary                                  |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k254221/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026