

**K230693 BIS™ Advance Monitoring System**Feb 26, 2024  
350 days to decisionK230693 · Product code: **OLW** · AnesthesiologySource: <https://www.510kdatabase.net/k230693/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Index-generating Electroencephalograph Software (OLW)
Date received	Mar 13, 2023
Decision date	Feb 26, 2024
Days to decision	350 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Covidien, LLC</b>
Location	Mansfield, MA, US
Contact	Moshe J Cohen
510(k) history	88 submissions · 85 cleared · 2010-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k230693/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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