

**K233448 Bactiseal EVD Catheter Sets**Dec 19, 2023  
60 days to decisionK233448 · Product code: **JXG** · Neurology  
Source: <https://www.510kdatabase.net/k233448/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Oct 20, 2023
Decision date	Dec 19, 2023
Days to decision	60 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Bactiseal Clear EVD Catheter Set

**APPLICANT**

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Company	<b>Integra Lifesciences Production Corporation</b>
Location	Mansfield, MA, US
Contact	Amanda Erwin
510(k) history	8 submissions · 8 cleared · 2021-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233448/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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