

**K181301 Smart External Drain (SED) System**Jun 14, 2018  
28 days to decisionK181301 · Product code: **JXG** · Neurology  
Source: <https://www.510kdatabase.net/k181301/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	May 17, 2018
Decision date	Jun 14, 2018
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aqueduct Critical Care, Inc.</b>
Location	Bothell, WA, US
Contact	Thomas Clement
510(k) history	4 submissions · 4 cleared · 2016-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181301/> 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 30, 2026