

K161605 Smart External Drain (SED) SystemOct 27, 2016
139 days to decisionK161605 · Product code: **JXG** · Neurology
Source: <https://www.510kdatabase.net/k161605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Shunt, Central Nervous System And Components (JXG)
Date received	Jun 10, 2016
Decision date	Oct 27, 2016
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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