

**K183374 GrayDuck Stent**Feb 26, 2019  
82 days to decisionK183374 · Product code: **IYE** · Radiology  
Source: <https://www.510kdatabase.net/k183374/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accelerator, Linear, Medical (IYE)
Date received	Dec 6, 2018
Decision date	Feb 26, 2019
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Poll Medical, LLC</b>
Location	Beaverton, OR, US
Contact	Adrian Polliack
510(k) history	1 submissions · 1 cleared · 2019-2019

**REGULATORY CONSULTANT**

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Consulting firm	<b>Allegiance Regulatory Consulting, LLC</b>
Contact	Alyssa Thomas

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k183374/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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