

**K161167 Seal Single-Use Biopsy Valve**May 26, 2016  
30 days to decisionK161167 · Product code: **OCX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k161167/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Irrigation/suction System (OCX)
Date received	Apr 26, 2016
Decision date	May 26, 2016
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Endochoice, Inc.</b>
Location	Charlotte, NC, US
Contact	Daniel Hoefler
510(k) history	27 submissions · 25 cleared · 2010-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k161167/> 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 24, 2026