

K160403 SmartStart Air/Water and Suction ValvesMay 19, 2016
97 days to decisionK160403 · Product code: **ODC** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k160403/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	Feb 12, 2016
Decision date	May 19, 2016
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Endochoice, Inc.
Location	Chalotte, NC, US
Contact	DANIEL HOEFER
510(k) history	27 submissions · 25 cleared · 2010-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160403/> Data sourced from FDA 510(k) public records (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. - Generated May 24, 2026