

K181509 Endorate Valve SetsJul 6, 2018
28 days to decisionK181509 · Product code: **OCX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k181509/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Irrigation/suction System (OCX)
Date received	Jun 8, 2018
Decision date	Jul 6, 2018
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Smartdata Suzhou Co., Ltd.
Location	Suzhou, CN
Contact	Cindy Ye
510(k) history	4 submissions · 4 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	DAVE YUNGVIRT

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

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