

**K191231 Andorate Auxiliary Water Connector, Andorate Valves Set**Jun 7, 2019  
30 days to decisionK191231 · Product code: **ODC** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k191231/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope Channel Accessory (ODC)
Date received	May 8, 2019
Decision date	Jun 7, 2019
Days to decision	30 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Accelerated Device Approval Services</b>
Contact	Rafael Aguila

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

---

510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191231/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated June 28, 2026