

K191366 Vacutore Air/Water Bottle Tubing

Sep 6, 2019
107 days to decision

K191366 · Product code: **OCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k191366/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Irrigation/suction System (OCX)
Date received	May 22, 2019
Decision date	Sep 6, 2019
Days to decision	107 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	Accelerated Device Approval Services
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)
