

K193250 Irrigation Tubing with CO2 or AirApr 6, 2020
133 days to decisionK193250 · Product code: **OCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k193250/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Irrigation/suction System (OCX)
Date received	Nov 25, 2019
Decision date	Apr 6, 2020
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Keymed (Medical and Industrial Equipment) , Ltd.
Location	Southend-On-Sea, GB
Contact	Andy Hollingsworth
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Olympus Surgical Tech America - Gyrus Acmi, Inc.
Contact	Mary Anne Patella

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

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