

K202922 END 200 Endoscopic TubesetJul 8, 2021
282 days to decisionK202922 · Product code: **FCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k202922/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Sep 29, 2020
Decision date	Jul 8, 2021
Days to decision	282 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Palliare , Ltd.
Location	Galway, IE
Contact	John O'Dea
510(k) history	6 submissions · 6 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	Palliare Ltd. C/O Promedic Consulting, LLC
Contact	Paul Dryden

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

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