

K230474 EVA5 InsufflatorMar 24, 2023
30 days to decisionK230474 · Product code: **FCX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k230474/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Insufflator, Automatic Carbon-dioxide For Endoscope (FCX)
Date received	Feb 22, 2023
Decision date	Mar 24, 2023
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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