

K222901 EVA15 insufflatorJan 27, 2023
126 days to decisionK222901 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k222901/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Sep 23, 2022
Decision date	Jan 27, 2023
Days to decision	126 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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