

K193520 EVA 15 InsufflatorJul 23, 2020
217 days to decisionK193520 · Product code: **HIF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k193520/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Insufflator, Laparoscopic (HIF)
Date received	Dec 19, 2019
Decision date	Jul 23, 2020
Days to decision	217 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193520/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026