

K243821 i-CutApr 25, 2025
134 days to decisionK243821 · Product code: **HET** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k243821/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, Gynecologic (and Accessories) (HET)
Date received	Dec 12, 2024
Decision date	Apr 25, 2025
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	A.M.I. Agency For Medical Innovations GmbH
Location	Feldkirch, AT
Contact	Anke Ristow
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243821/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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