FDA 510(k) Premarket Notification

K243821 i-Cut

CLEARED

Apr 25, 2025
134 days to decision

K243821 · Product code: **HET** · Obstetrics & Gynecology
Source: 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