

K250212 LapBox Power Tissue Containment SystemApr 15, 2025
81 days to decisionK250212 · Product code: **PMU** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k250212/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Containment System, Laparoscopic Power Morcellation, With Instrument Port (PMU)
Date received	Jan 24, 2025
Decision date	Apr 15, 2025
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ark Surgical
Location	13 Wadi El Haj, IL
Contact	Stav Tori
510(k) history	1 submissions · 1 cleared · 2025-2025

REGULATORY CONSULTANT

Consulting firm	ProMedoss, Inc.
Contact	Bosmat Friedman-Cox

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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