

K221365 LapBox Tissue Containment Removal SystemAug 25, 2022
105 days to decisionK221365 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	May 12, 2022
Decision date	Aug 25, 2022
Days to decision	105 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ark Surgical, Ltd.
Location	Nazareth, IL
Contact	Stav Tori
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	ProMedoss, Inc.
Contact	Bosmat Friedman

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

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