

K252442 Kii Structural Balloon Access SystemOct 31, 2025
88 days to decisionK252442 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k252442/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Aug 4, 2025
Decision date	Oct 31, 2025
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Applied Medical Resources Corp.
Location	Rancho Santa, CA, US
Contact	Derek Greene
510(k) history	45 submissions · 45 cleared · 2001-2025

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