

**K211043 Alexis Contained Extraction System**Mar 31, 2022  
357 days to decisionK211043 · Product code: **GCJ** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k211043/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Apr 8, 2021
Decision date	Mar 31, 2022
Days to decision	357 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Applied Medical Resources Corporation</b>
Location	Rancho Santa, CA, US
Contact	Apeksha Shanbhag
Website	<a href="https://www.appliedmedical.com/">https://www.appliedmedical.com/</a>
510(k) history	12 submissions · 12 cleared · 2017-2026

Applied Medical Resources Corporation is a medical device manufacturer specializing in minimally invasive surgical instruments and access systems, with a manufacturing facility in Rancho Santa, California. The company develops a broad portfolio of surgical tools for general, plastic, and gynecological procedures. Applied Medical has received FDA 510(k) clearances from total submissions since 2017. The company's regulatory focus centers on General & Plastic Surgery devices, which represent the majority of its cleared portfolio. The most recent clearance was in 2026, demons...

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