

K190331 Applied Medical Laparoscopic Linear CutterNov 22, 2019
281 days to decisionK190331 · Product code: **GDW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190331/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Staple, Implantable (GDW)
Date received	Feb 14, 2019
Decision date	Nov 22, 2019
Days to decision	281 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Applied Medical Resources Corporation
Location	Rancho Santa, CA, US
Contact	Aditi Iyengar
Website	https://www.appliedmedical.com/
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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