

K182024 Dissecting Balloon SystemAug 30, 2018
31 days to decisionK182024 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k182024/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Jul 30, 2018
Decision date	Aug 30, 2018
Days to decision	31 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182024/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026