

K211234 RedExSep 17, 2021
147 days to decisionK211234 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k211234/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Apr 23, 2021
Decision date	Sep 17, 2021
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Advanced Surgical Concepts, Ltd.
Location	Bray, IE
Contact	Edward Hyland
510(k) history	3 submissions · 1 cleared · 2016-2021

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Jonathan S. Kahan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211234/> 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 26, 2026