

K232701 Guardenia (GAR-1)Sep 29, 2023
24 days to decisionK232701 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k232701/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Sep 5, 2023
Decision date	Sep 29, 2023
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Advanced Surgical Concepts
Location	North Attleboro, MA, US
Contact	Edward Hyland
510(k) history	9 submissions · 9 cleared · 2007-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232701/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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