

K213597 MultiCut SoloJan 18, 2023
432 days to decisionK213597 · Product code: **GCJ** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k213597/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Nov 12, 2021
Decision date	Jan 18, 2023
Days to decision	432 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Asclepion Laser Technologies GmbH
Location	Chelmsford, MA, US
Contact	Tom Gruender
510(k) history	29 submissions · 29 cleared · 2004-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k213597/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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