

K253541 EZ-Close™ (EZ Close Port Site Closing Device, EZ Close MAX Port Site Closing Device, EZ Close II Port Site Closing Device)

Jul 24, 2026
252 days to decision

K253541 · Product code: **GCJ** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k253541/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laparoscope, General & Plastic Surgery (GCJ)
Date received	Nov 14, 2025
Decision date	Jul 24, 2026
Days to decision	252 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Medical Impact
Location	Gyeonggi-Do, KR
Contact	Hanna Kim
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k253541/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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