

K254271 CAPRIFeb 26, 2026
58 days to decisionK254271 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k254271/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 30, 2025
Decision date	Feb 26, 2026
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	ORO Co., Ltd.
Location	Gimpo-Si, KR
Contact	James Hoon Lim
Website	https://www.oromedical.co.kr
510(k) history	1 submissions · 1 cleared · 2026-2026

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