

K251632 Optimas MAX SystemJun 26, 2025
29 days to decisionK251632 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251632/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 28, 2025
Decision date	Jun 26, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Inmode , Ltd.
Location	Yokneam, IL
Contact	Suhair Francis
510(k) history	15 submissions · 15 cleared · 2019-2026

REGULATORY CONSULTANT

Consulting firm	Hogan Lovells US LLP
Contact	Janice M. Hogan

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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