

K221571 InMode Multi-systemJun 30, 2022
30 days to decisionK221571 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k221571/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 31, 2022
Decision date	Jun 30, 2022
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	A. Stein - Regulatory Affairs Consulting , Ltd.
Contact	Amit Goren

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

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