FDA 510(k) Premarket Notification

K221571 InMode Multi-system

CLEARED

Jun 30, 2022
30 days to decision

K221571 · Product code: **GEX** · General & Plastic Surgery
Source: 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