

K201285 InMode Evolve System with the Tone ApplicatorMar 5, 2021
296 days to decisionK201285 · Product code: **IPF** · Physical Medicine
Source: <https://www.510kdatabase.net/k201285/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	May 13, 2020
Decision date	Mar 5, 2021
Days to decision	296 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k201285/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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