

K210877 Evolve System with the T3 ApplicatorJul 19, 2021
117 days to decisionK210877 · Product code: **PBX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k210877/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Mar 24, 2021
Decision date	Jul 19, 2021
Days to decision	117 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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