FDA 510(k) Premarket Notification

K210492 InMode RF Pro System

CLEARED

Jul 12, 2021
143 days to decision

K210492 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k210492/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 19, 2021
Decision date	Jul 12, 2021
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Inmode MD , Ltd.**
Location	Kfar Saba, IL
Contact	Amit Goren
510(k) history	21 submissions · 21 cleared · 2013-2021

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