FDA 510(k) Premarket Notification

K200947 InMode System with the Morhpeus8 Applicators

CLEARED

Jul 2, 2020
85 days to decision

K200947 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200947/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 8, 2020
Decision date	Jul 2, 2020
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k200947/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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