

**K192695 InMode System with the Morpheus8 (Fractora)
Applicators**Dec 27, 2019
92 days to decisionK192695 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k192695/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 26, 2019
Decision date	Dec 27, 2019
Days to decision	92 days
Third-party review	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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192695/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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