

K191855 EmFace DeviceOct 29, 2019
111 days to decisionK191855 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191855/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Massager, Vacuum, Radio Frequency Induced Heat (PBX) |
| Date received | Jul 10, 2019 |
| Decision date | Oct 29, 2019 |
| Days to decision | 111 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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|----------------|---|
| 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/k191855/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026