

K214015 Palm NRG cellulite body device (model: Palm NRG body device)Sep 26, 2022
278 days to decisionK214015 · Product code: **PBX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k214015/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Dec 22, 2021
Decision date	Sep 26, 2022
Days to decision	278 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Heat IN A Click, LLC
Location	Dania, FL, US
Contact	Guy Levi
510(k) history	6 submissions · 6 cleared · 2015-2025

REGULATORY CONSULTANT

Consulting firm	Guangzhou GLOMED Biological Technology Co., Ltd.
Contact	Cassie Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k214015/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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