

K250916 WinForth (LM-E470KA)Aug 14, 2025
140 days to decisionK250916 · Product code: **PBX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250916/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Massager, Vacuum, Radio Frequency Induced Heat (PBX)
Date received	Mar 27, 2025
Decision date	Aug 14, 2025
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	Shenzhen Leaflife Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Cheng Qiang
510(k) history	7 submissions · 7 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	Aestheticcert Compliance, LLC
Contact	Asher Zeng

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

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