FDA 510(k) Premarket Notification

K250916 WinForth (LM-E470KA)

CLEARED

Aug 14, 2025
140 days to decision

K250916 · Product code: **PBX** · General & Plastic Surgery
Source: 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