FDA 510(k) Premarket Notification

CLEARED

K254047 Hair Removal Device (CT10, CT10 Pro, CT11, CT11 Pro, CT12, CT12 Pro, CTU05, CTU07, CTU09, CTU012, CTU015, CTU X, DT015 Pro, DT015, DT017 Pro, DT017, DT025 Pro, DT025)

Mar 11, 2026
84 days to decision

K254047 · Product code: **OHT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k254047/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Dec 17, 2025
Decision date	Mar 11, 2026
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Chuangtong Yigou Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Kingway Hong
510(k) history	2 submissions · 2 cleared · 2025-2026

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Candice Qiu

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