FDA 510(k) Premarket Notification

CLEARED

K251000 Hand-held Hair Removal Device (FZ-200A, FZ-201, FZ-202, CT05, CT06, CT07, CT08, CT09)

Jun 30, 2025
90 days to decision

K251000 · Product code: **OHT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k251000/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Apr 1, 2025
Decision date	Jun 30, 2025
Days to decision	90 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