

K250308 Hair Growth Device (KCA441-200, KCA441-120, KCA441-88, KCA441-56, KCA441-200S, KCA441-120S, KCA441-88S, KCA441-56S, KCA451-200, KCA451-120, KCA451-88, KCA451-56, KCA451-200S, KCA451-120S, KCA451-88S, KCA451-56S)Apr 29, 2025
85 days to decisionK250308 · Product code: **OAP** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k250308/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	Feb 3, 2025
Decision date	Apr 29, 2025
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dongguan Boyuan Intelligent Technology Co.,Ltd
Location	Dongguan, CN
Contact	Jinlong Li
510(k) history	4 submissions · 4 cleared · 2024-2025

REGULATORY CONSULTANT

Consulting firm	Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.
Contact	Reanny Wang

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