

K213025 Laser hair growth helmetMay 12, 2022
233 days to decisionK213025 · Product code: **OAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213025/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	Sep 21, 2021
Decision date	May 12, 2022
Days to decision	233 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kam Yuen Plastic Products , Ltd.
Location	Zhongshan, CN
Contact	Anna Dan
510(k) history	5 submissions · 5 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	Guangdong Jianda Medical Technology Co., Ltd.
Contact	Jett Lee

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

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