

K202631 iHelmet Laser CombDec 8, 2020
88 days to decisionK202631 · Product code: **OAP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202631/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	Sep 11, 2020
Decision date	Dec 8, 2020
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Slinph Technologies Co., Ltd.
Location	Shenzhen, CN
Contact	Jian Zou
510(k) history	3 submissions · 3 cleared · 2017-2020

REGULATORY CONSULTANT

Consulting firm	Guangzhou GLOMED Biological Technology Co., Ltd.
Contact	Cassie Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202631/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026