

**K190467 iHelmet Hair Growth System**Dec 26, 2019  
303 days to decisionK190467 · Product code: **OAP** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k190467/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Comb, Hair (OAP)
Date received	Feb 26, 2019
Decision date	Dec 26, 2019
Days to decision	303 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Sk Medical Device International Corp.</b>
Contact	S K

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k190467/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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