

**K210545 Infrared Red blue LED light heat beauty machine,  
Infrared Red blue LED light heat beauty machine, Infrared Red  
blue LED light heat beauty machine**May 20, 2022  
449 days to decisionK210545 · Product code: **OLP** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k210545/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Powered Light Based Laser For Acne (OLP)
Date received	Feb 25, 2021
Decision date	May 20, 2022
Days to decision	449 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Marci Beauty, Inc.</b>
Location	Las Vegas, NV, US
Contact	Shaul Rappaport
510(k) history	1 submissions · 1 cleared · 2022-2022

**REGULATORY CONSULTANT**

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Consulting firm	<b>Wenzhou Cytech Information Service Co., Ltd.</b>
Contact	Helen Nan

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k210545/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 27, 2026