

**K212314 IPL Hair Removal Device**Oct 21, 2021  
90 days to decisionK212314 · Product code: **OHT** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k212314/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Jul 23, 2021
Decision date	Oct 21, 2021
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Zhongshan Bisen Plastic Electronic Products Co., Ltd.</b>
Location	Zhong Shan, CN
Contact	Rao Guanhua
510(k) history	2 submissions · 2 cleared · 2017-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Joyantech Consulting Co., Ltd.</b>
Contact	Mark Leung

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.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212314/> 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 26, 2026