

K212897 IPL Hair Removal Device, model: AI01Nov 4, 2021
55 days to decisionK212897 · Product code: **OHT** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k212897/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Sep 10, 2021
Decision date	Nov 4, 2021
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Century Dongyuan Technology CO , Ltd.
Location	Shenzhen, CN
Contact	He Wang
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	Qimmiq Medical Consulting Service Co., Ltd.
Contact	You Yijie

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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