

K243085 IPL Hair Removal Device (DE03A-W, DE03A-P, DE03A-V, DE03A-G, DE03B-W, DE03B-P, DE03B-V, DE03B-G)Dec 21, 2024
82 days to decisionK243085 · Product code: OHT · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k243085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Sep 30, 2024
Decision date	Dec 21, 2024
Days to decision	82 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Zhuzhou Goldenhot Medical Technology Co., Ltd.
Location	Zhuzhou, CN
Contact	Xianwu Liu
510(k) history	3 submissions · 3 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	Feiyong Drug & Medical Consulting Technical Service Group
Contact	Candice Qiu

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243085/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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