

**K230490 PMD Clean Acne, Model: 4004-CABLUE-NA,
4004-GREY-NA, 4004-YELLOW-NA, 4004-PSTO-NA, 4004-LPUR-
NA, 4004-CABLUE-NA-INT, 4004-GREY-INT, 4004-YELLOW-INT,
4004-PSTO-INT, 4004-LPUR-INT**Oct 27, 2023
246 days to decisionK230490 · Product code: **OLP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k230490/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Powered Light Based Laser For Acne (OLP)
Date received	Feb 23, 2023
Decision date	Oct 27, 2023
Days to decision	246 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Dongguan Hunter Electronic Technology Co., Ltd.
Location	Guangdong, CN
Contact	Hunter Ye
510(k) history	2 submissions · 2 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	Feiyong Drug & Medical Consulting Technical Service Group
Contact	Tracy Che

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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