FDA 510(k) Premarket Notification

CLEARED

K231613 Intense pulsed light device, Model(s): DE01A-B, DE01A-G, DE01B-B, DE01B-G, DE01C-B, DE01C-G, DE02A-B, DE02A-G, DE02B-B, DE02B-G, DE02C-B, DE02C-G.

Jul 31, 2023
59 days to decision

K231613 · Product code: **OHT** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k231613/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over-the-counter Hair Removal (OHT)
Date received	Jun 2, 2023
Decision date	Jul 31, 2023
Days to decision	59 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	Liu Xianwu
510(k) history	3 submissions · 3 cleared · 2023-2024

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Candice Qui

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