

**K242755 Medical Diode Laser Systems (VELAS II-30B, VELAS II-30A, GBOX-15AB, GBOX-20B, CHEESE II-10B)**

May 19, 2025  
249 days to decision

K242755 · Product code: ILY · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k242755/>

**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lamp, Infrared, Therapeutic Heating (ILY)
Date received	Sep 12, 2024
Decision date	May 19, 2025
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Gigalaser Company , Ltd.</b>
Location	Wuhan, CN
Contact	Xinxing Nie
510(k) history	4 submissions · 4 cleared · 2024-2025

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k242755/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026