

K230047 Medical Diode Laser SystemsMar 4, 2024
423 days to decisionK230047 · Product code: **NVK** · Dental
Source: <https://www.510kdatabase.net/k230047/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Dental, Soft Tissue (NVK)
Date received	Jan 6, 2023
Decision date	Mar 4, 2024
Days to decision	423 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k230047/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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