

K232885 Dawn Diode Laser SystemFeb 28, 2024
163 days to decisionK232885 · Product code: **NVK** · Dental
Source: <https://www.510kdatabase.net/k232885/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Dental, Soft Tissue (NVK)
Date received	Sep 18, 2023
Decision date	Feb 28, 2024
Days to decision	163 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shanghai Wonderful Opto-Electrics Tech.Co.,Ltd
Location	Shanghai, CN
Contact	Lily Zhou
510(k) history	6 submissions · 6 cleared · 2016-2024

REGULATORY CONSULTANT

Consulting firm	Aisnwei Information Technology Co., Ltd.
Contact	Fu Ailing

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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