

K253309 SOGA Lasers therapy system family of Aurora handpiece (Aurora-S)

May 19, 2026
232 days to decision

K253309 · Product code: **NVK** · Dental
Source: <https://www.510kdatabase.net/k253309/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Dental, Soft Tissue (NVK)
Date received	Sep 29, 2025
Decision date	May 19, 2026
Days to decision	232 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SOGA Lasers therapy system family of the Dental diode laser (ILaser III Pro)

APPLICANT

Company	Shenzhen Soga Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Zhang Sha
510(k) history	3 submissions · 3 cleared · 2022-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k253309/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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