FDA 510(k) Premarket Notification

CLEARED

K260765 Gemini NOVA 810+980 Soft Tissue Laser

Mar 10, 2026
1 days to decision

K260765 · Product code: **NVK** · Dental
Source: https://www.510kdatabase.net/k260765/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Dental, Soft Tissue (NVK)
Date received	Mar 9, 2026
Decision date	Mar 10, 2026
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Azena Medical, LLC**
Location	Walnut Creek, CA, US
Contact	Lindsay Tilton
510(k) history	4 submissions · 4 cleared · 2015-2026

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	DAVE YUNGVIRT

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