

K210350 Gemini 2 810+980 Soft Tissue LaserNov 18, 2021
283 days to decisionK210350 · Product code: **NVK** · Dental
Source: <https://www.510kdatabase.net/k210350/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Dental, Soft Tissue (NVK)
Date received	Feb 8, 2021
Decision date	Nov 18, 2021
Days to decision	283 days
Third-party review	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

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