

**K213428 EdgePro**Dec 22, 2021  
62 days to decisionK213428 · Product code: **NVK** · Dental  
Source: <https://www.510kdatabase.net/k213428/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Laser, Dental, Soft Tissue (NVK)
Date received	Oct 21, 2021
Decision date	Dec 22, 2021
Days to decision	62 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biolase, Inc.</b>
Location	Irvine, CA, US
Contact	Ed Balcos
510(k) history	10 submissions · 10 cleared · 2014-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k213428/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026