

**K232222 Primo Dental Laser (Primo, Primo Komfort, Primo Lite, Primo Blue, and Primo Triplo)**Nov 27, 2023  
124 days to decisionK232222 · Product code: **NVK** · Dental  
Source: <https://www.510kdatabase.net/k232222/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser, Dental, Soft Tissue (NVK)
Date received	Jul 26, 2023
Decision date	Nov 27, 2023
Days to decision	124 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medency S.R.L.</b>
Location	Vicenza, IT
Contact	Alessandro Zorgati
510(k) history	2 submissions · 2 cleared · 2023-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k232222/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 25, 2026