

**K221851 Lumina-PTFE Titanium**Dec 8, 2023  
529 days to decisionK221851 · Product code: **NPK** · Dental  
Source: <https://www.510kdatabase.net/k221851/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Barrier, Synthetic, Intraoral (NPK)
Date received	Jun 27, 2022
Decision date	Dec 8, 2023
Days to decision	529 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Criteria Industria E Comercio DE Produtos Mediciniais</b>
Location	Sao Carlos, BR
Contact	Andre Hamar Braga
510(k) history	1 submissions · 1 cleared · 2023-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Pr Servicos Regulatorios Administrativos Ltda</b>
Contact	Graziela Brum

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221851/> 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 26, 2026