

**K260138 LUNE PureHygiene**May 29, 2026  
133 days to decisionK260138 · Product code: **GEX** · Dental  
Source: <https://www.510kdatabase.net/k260138/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 16, 2026
Decision date	May 29, 2026
Days to decision	133 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Enamel Pure</b>
Location	Worcester, MA, US
Contact	Nathan Monty
510(k) history	2 submissions · 2 cleared · 2024-2026

**REGULATORY CONSULTANT**

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Consulting firm	<b>Omnee Strategic Solutions, Inc.</b>
Contact	Dhaval Saraiya

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/k260138/> 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 June 5, 2026