FDA 510(k) Premarket Notification

K260138 LUNE PureHygiene

CLEARED

May 29, 2026
133 days to decision

K260138 · Product code: **GEX** · Dental
Source: https://www.510kdatabase.net/k260138/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Omnee Strategic Solutions, Inc.**
Contact	Dhaval Saraiya

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov