May 29, 2026

Enamel Pure
% Dhaval Saraiya
RA/QA Consultant
Omnee Strategic Solutions, Inc.
7 Desrosiers Landing
South Grafton, Massachusetts 01560

Re: K260138
Trade/Device Name: LUNE PureHygiene
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: January 28, 2026
Received: April 28, 2026

Dear Dhaval Saraiya:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the Quality Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260138

Please provide the device trade name(s).

LUNE PureHygiene

Please provide your Indications for Use below.

Enamel Pure Lune PureHygiene is indicated for the following in hard tissue:
• Reduction of bacterial level (decontamination)
• Aiding in the reduction of mineral loss in dental enamel

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

K260138 - 510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the LUNE PureHygiene 510(k) premarket notification.

Sponsor:

Enamel Pure Inc.
Nathan Monty
17 Briden Street
Worcester, MA 01605

Contact Person:

Dhaval S.
Omnee Strategic Solutions, Inc.
Regulatory/Quality Consultant
Email: info@omneestrategicsolutions.com

Date:

May 28, 2026

Subject Device:

Trade Name: LUNE™ PureHygiene
Common Name: Dental Laser System
Classification Name: GEX – Powered Laser Surgical Instrument (21 CFR 878.4810)

Predicate Device(s):

Predicate Device:	K234085	LUNE™ PureHygiene	GEX	Enamel Pure
Reference Device:	K221761	Solea	GEX	Convergent Dental

Device Description:
The LUNE PureHygiene System is a mobile, cart-based dental treatment system comprised of a base console, a pneumatic footswitch, scanned laser beam delivery, and handpieces that uses a pulsed CO_2 laser energy to reduce/remove bacteria and plaque, and purify dental enamel by removing/reducing embedded carbonate from dental enamel to increase resistance to acid and reduce demineralization, such as cavities. Enamel Pure's LUNE PureHygiene system is controlled through discrete pushbuttons and preset settings through a processor and software.

Intended Use and Indications for Use:
Enamel Pure Lune Laser System is indicated for the following in hard tissue:

- Reduction of bacterial level (decontamination)
- Aiding in the reduction of mineral loss in dental enamel

Summary of Technological Characteristics:
The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** The intended use is identical to the intended use cleared in K234085.
- **Indications for Use:** The indications for use are similar to the indications for use cleared in K234085 and K221761.
- **Design Features:** The design features are identical to those in currently marketed devices cleared in K234085.

Summary of Performance Data (Nonclinical and/or Clinical):

- **Non-Clinical Testing:**
  Design verification activities, including ex vivo testing of human teeth , were performed to support the additional indication for aiding in the reduction of mineral loss in dental enamel. These design verification activities demonstrate that (1) CO_2 laser treatment with the LUNE PureHygiene System produces a consistent and statistically significant reduction in enamel carbonate content; and (2) that CO_2 laser treatment with the LUNE PureHygiene System produces a statistically significant reduction in acid-mediated enamel demineralization depth.

- **Clinical Testing:**
  N/A

Substantial Equivalence
The LUNE PureHygiene system has been shown to be substantially equivalent to the predicate device. Results of the nonclinical testing demonstrate that the device performs as intended for its proposed use and do not raise any new questions of safety or effectiveness.

Property or Characteristic	**Proposed Device** LUNE PureHygiene	**Predicate Device** LUNE PureHygiene (K234085)	**Reference Device Solea** (K221761)	**Proposed Device compared with Reference Device**
Operating Voltage	100V-240V	100V-240V	100V-240V	Identical
Frequency	50/60 Hz	50/60 Hz	50/60 Hz	Identical
Main Control	Main Power Switch	Main Power Switch	Main Power Switch	Identical
Remote Interruption	Remote Interlock - Rear	Remote Interlock - Rear	Remote Interlock - Rear	Identical
Disable Control	Emergency Stop Button	Emergency Stop Button	Emergency Stop Button	Identical
Laser Source	Treatment - CO2 Aiming - Diode laser	Treatment - CO2 Aiming - Diode laser	Treatment - CO2 Aiming - Diode laser	Identical

Property or Characteristic	Proposed Device LUNE PureHygiene	Predicate Device LUNE PureHygiene (K234085)	Reference Device Solea (K221761)	Proposed Device compared with Reference Device
Average Power	0 to 2W	0 to 2W	0 to 30W	93% lower power range than Reference Device
Laser Activation	Footswitch	Footswitch	Footswitch	Identical
Laser Classification	Treatment – Class IV Aiming – Class 2	Treatment – Class IV Aiming – Class 2	Treatment – Class IV Aiming – Class 2/3R	Similar, lower Class Aiming Laser
Operating Modes	Treatment laser – Pulsed Aiming Diode - Continuous	Treatment laser – Pulsed Aiming Diode - Continuous	Ablation laser – Pulsed Aiming Diode - Continuous	Similar, non-ablative Laser
Laser Wavelength	10.6 µm ± 0.4 µm	10.6 µm ± 0.4 µm	9.25 µm ± 0.4 µm	Functionally Similar
Aiming Beam	Laser Diode; < 0.5 mW	Laser Diode; < 0.5 mW	520 nm Diode; < 5 mW	Functionally Similar
Delivery System	Articulating Arm and handpiece	Articulating Arm and handpiece	Articulating Arm and handpiece	Identical
Footswitch	Pneumatic, IP68	Pneumatic, IP68	Wired	Functionally Similar
Handpiece	Medical grade Radel	Medical grade Radel	Stainless Steel	Functionally Similar
Sterilization Method	Steam Autoclave (Handpiece only)	Steam Autoclave (Handpiece only)	Steam Autoclave (Handpiece only)	Identical