March 25, 2024

Enamel Pure
℅ Dhaval Saraiya
Regulatory Affairs and Quality Assurance Consultant
Omnee Strategic Solutions, Inc.
7 Desrosiers Landing
South Grafton, Massachusetts 01560

Re: K234085
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: December 22, 2023
Received: December 26, 2023

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K234085

Device Name

LUNE™ PureHygiene

Indications for Use *(Describe)*

Enamel Pure LUNE PureHygiene is indicated for the following in dental hard tissue:
• Reduction of bacterial level (decontamination)

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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K234085 - 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: omneestrategicsol@gmail.com

Date:

Mar 21, 2024

Subject Device:

Trade Name: LUNE™ PureHygiene
Common Name: Dental Laser System
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology - (21 CFR 878.4810)
GEX – Powered Laser Surgical Instrument

Predicate Device(s):

Primary Predicate:	K193486	Epic Pro/Hygiene	Biolase
Reference Device:	K221761	Solea	Convergent Dental

Purpose and Device Description:

The purpose of this submission is to request clearance for the new LUNE PureHygiene. The subject LUNE PureHygiene is a mobile, cart-based dental treatment system comprised of a base console, a pneumatic footswitch, and handpieces that uses a pulsed CO_2 laser energy to reduce/remove plaque and embedded carbonate from dental enamel.

Intended Use and Indications for Use:

Enamel Pure LUNE PureHygiene is indicated for the following in dental hard tissue:

- Reduction of bacterial level (decontamination)

Summary of Technological Characteristics:

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

- **Intended Use:** The intended use is similar to the intended use cleared in K193486.

- **Indications for Use:** The indications for use are similar to the indications for use cleared in K193486.
- **Design Features:** The design features are similar to those in currently marketed devices cleared in K193486 and K221761.

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

- **Non-Clinical Tests:**
  - Electrical Safety Testing per IEC 60601-1
  - EMC Testing per IEC 60601-1-2
  - Laser Safety Testing per IEC 60601-2-22 & IEC 60825-1
  - Software Verification and Validation
  - Design Verification - tooth temperature, bacterial reduction, and user validation
  - Reprocessing Validation (cleaning and sterilization) per the FDA Reprocessing Guidance
  - Biocompatibility Assessment per ISO 10993-1 and the FDA Biocompatibility Guidance

- **Clinical Tests:**
  - N/A

Substantial Equivalence

The LUNE PureHygiene has been shown to be substantially equivalent to the predicate device. Results of the non-clinical tests indicate that the device will perform within the intended uses.

Property or Characteristic	**Proposed Device** LUNE PureHygiene	**Predicate Device** Epic Pro/Hygiene (K193486)	**Reference Device Solea** (K221761)
FDA Product Code(s)	GEX	GEX	GEX
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	21 CFR 878.4810
Classification Name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument
Indications for Use	Enamel Pure LUNE PureHygiene is indicated for the following in dental hard tissue: • Reduction of bacterial level (decontamination)	Biolase Epic Pro/Hygiene is indicated for the following: • Reduction of bacterial level (decontamination) and inflammation Please refer to K193486 for a complete list of indications.	The Solea system is indicated for the following: • Aiding in the reduction of mineral loss in dental enamel • Ablation of hard tissue for caries removal and cavity prevention • Incision, excision, vaporization, coagulation and hemostasis of soft tissue in the oral cavity • Cutting, shaving, contouring and resection of oral osseous tissue (both)
Operating Voltage	100V-240V	100V-240V	100V-240V

Property or Characteristic	Proposed Device LUNE PureHygiene	Predicate Device Epic Pro/Hygiene (K193486)	Reference Device Solea (K221761)
Frequency	50/60 Hz	50/60 Hz	50/60 Hz
Main Control	Main Power Switch	Main Power Switch	Main Power Switch
Remote Interruption	Remote Interlock - Rear	Remote Interlock - Rear	Remote Interlock - Rear
Disable Control	Emergency Stop Button	Emergency Stop Button	Emergency Stop Button
Laser Source	Treatment - CO_2 Aiming - Diode laser	Treatment - Semi-conductor diode Aiming - Diode laser	Treatment - CO_2 Aiming - Diode laser
Laser Activation	Footswitch	Footswitch	Footswitch
Laser Classification	Treatment – Class IV Aiming – Class 2	Treatment – Class IV Aiming – Class 2	Treatment – Class IV Aiming – Class 2/3R
Delivery System	Articulating Arm and handpiece	Fiber optic cable, handpiece and disposable tips	Articulating Arm and handpiece
Handpiece	Medical grade Radel	Stainless Steel	Stainless Steel
Sterilization Method	Steam Autoclave (Handpiece only)	Steam Autoclave (Handpiece only)	Steam Autoclave (Handpiece only)