



October 14, 2025

Meta Systems Co., Ltd.
% Dave Yungvirt
CEO
Third Party Review Group, LLC
7 Giralda Farms, Suite 120A
Madison, New Jersey 07940

Re: K253461
Trade/Device Name: Demi Pro
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet activator for polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: October 7, 2025
Received: October 7, 2025

Dear Dave Yungvirt:

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.

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

510(k) Number (if known)

K253461

Device Name

Demi Pro

Indications for Use (Describe)

The Demi Pro is an LED visible light curing unit intended for polymerization of light-cured materials by dental professionals. It is also intended to provide illumination to aid in visualization during oral procedures.

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.

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510(k) Summary

K253461

10 October, 2025

Contact Details

Applicant Name	META SYSTEMS CO., LTD.
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Device Name

Device Trade Name	Demi Pro
Common Name	Ultraviolet activator for polymerization
Classification Name	Activator, Ultraviolet, For Polymerization
Regulation Number	872.6070
Product Code(s)	EBZ

Legally Marketed Predicate Devices

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K220471	VALO X	EBZ
K170529	Delight Ortho	EBZ

Device Description Summary

General information:

The Demi Pro is a pen-style cordless curing light used for the polymerization of light cured dental material and is powered by a rechargeable lithium-ion battery pack. An intraoral transillumination tip is available as an additional accessory. It is also intended to provide illumination to aid in visualization during oral procedures.

Principle of operation:

The LED Light Curing System operates by emitting high-intensity blue light from a powerful LED to activate the photo initiators contained in the resin, thereby initiating polymerization (curing).

Wavelength range

- Usable wavelength range: 380 nm – 515 nm
- Peak wavelengths: 400 nm, 460 nm

Light intensity levels

- PLS STD: 1100 -1330 mW/cm²
- PLS HIGH: 2200 – 2500 mW/cm²
- ORTHO: 2500 mW/cm²
- DIAGNOSIS: 20 – 24 mW

Duty cycle

- PLS STD: 20 sec ON / 60 sec OFF
- PLS HIGH: 5 sec ON / 60 sec OFF
- ORTHO: 3 sec x 3 times ON / 60 sec OFF
- DIAGNOSIS: 60 sec ON / 60 sec OFF

Waterproof rating: IPX4 (Applies to Handpiece)

Intended Use/Indications for Use

The Demi Pro is an LED visible light curing unit intended for polymerization of light-cured materials by dental professionals. It is also intended to provide illumination to aid in visualization during oral procedures.

Indications for Use Comparison

Predicate Device #1 [VALO X, K220471]

VALO X curing light is a source of illumination for curing photo-activated dental restorative materials and adhesives. It is also intended to provide illumination to aid in visualization during oral procedures.

VALO X curing light accessory/diffusor lenses are not intended for complete cure of photo-activated materials and adhesives.

Predicate Device #2 [Delight Ortho, K170529]

For light curing polymerization of dental composites, luting materials, cements and other

light cured materials.

Technological Comparison

The Demi Pro curing light demonstrates technological characteristics that are substantially equivalent to those of the predicate device, VALO X and Delight Ortho. All three devices are designed for the polymerization of light-cured dental materials using high-intensity LED light sources operating within a comparable wavelength range (380–515 nm). The curing modes provided by Demi Pro (Standard, High, and Ortho) are similar in function and output intensity to those of the predicate device, ensuring equivalent clinical performance.

All three devices feature an ergonomic design and portability and are intended for use by qualified dental professionals.

In particular, both the Demi Pro and VALO X are equipped with a two-button control system with visual indicators, enabling the user to select the curing mode and monitor the device status. In addition, each device includes a diagnostic light mode that utilizes similar light output and spectral characteristics to enhance clinical visualization.

In terms of construction, the materials used in both Demi Pro and VALO X are comparable. The main housing is made of anodized aluminum, and the optical components are constructed from similar thermoplastics and optical polymers, including TPX and polycarbonate blends. Magnetized lens attachment systems are present in both devices to facilitate easy interchange of accessories.

The Demi Pro device is powered by a rechargeable 3.7V lithium-ion battery with a capacity similar to those used in the VALO X and Delight Ortho devices. While VALO X offers additional AC power capability, the energy sources are functionally comparable for their intended use.

The fundamental operating principle of Demi Pro and VALO X is based on LED-driven photopolymerization, and both include a range of accessories that support clinical versatility, such as curing tips and transillumination aids.

In summary, the Demi Pro shares the key technological characteristics of the predicate devices in terms of design, materials, operating principle, power source, and performance specifications.

These similarities support the conclusion that the Demi Pro is substantially equivalent to the predicate devices (VALO X and Delight Ortho).

Non-Clinical and/or Clinical Test Summary & Conclusions

Guidance for Industry and FDA Staff - Dental Curing Lights - Premarket Notification [510(k)] Submissions

The test results showed that Demi Pro has the same wavelength band, similar light intensity, and output characteristics as Valo X, and the polymerization depth measurement results also confirmed equivalent performance.

Both products use LED as a light source, adopt Li-ion batteries as a power source, and the LED module temperature control function to prevent risks due to temperature rise is also applied in the same way.

Therefore, Demi Pro is considered a medical device that is substantially equivalent in performance to the legally marketed predicate device [VALO X, K K220471].

No clinical trials have been conducted.

Study results and considering the provisions of ISO 10993-1:2018, as well as FDA Guidance "Use of International Standard ISO 10993, 'Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process", dated 20. September 2020, it is concluded that the device Demi Pro is evaluated as biocompatible if manufactured appropriately and applied in compliance with its intended purpose as outlined in the manufacturer's Instructions for Use.