May 30, 2025

GENOSS Co., Ltd.
Jiyeon Lee
Regulatory affair
12F, 76, Changnyong-daero 256beon-gil, Yeongtong-gu,
Suwon-si, Gyeonggi-do, Republic of Korea

Re: K242386
Trade/Device Name: Bluemoon
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet activator for polymerization
Regulatory Class: Class II
Product Code: EBZ

Dear Jiyeon Lee:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 5, 2025. Specifically, FDA is updating this SE Letter to correct the official correspondent as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Michael Adjodha, OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices, 301-796-6276, Michael.Adjodha@fda.hhs.gov.

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

May 5, 2025

GENOSS Co., Ltd.
Jiyeon Lee
Regulatory affair
12F, 76, Changnyong-daero 256beon-gil, Yeongtong-gu
Manufacturing site: 3F, 4F, 5F, D-factory, 56, Changnyong-da
Suwon-si, Gyeonggi-do
China

Re: K242386
Trade/Device Name: Bluemoon
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator For Polymerization
Regulatory Class: Class II
Product Code: EBZ
Dated: September 8, 2024
Received: April 29, 2025

Dear Jiyeon Lee:

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,

Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., 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.

510(k) Number *(if known)*
K242386

Device Name
Bluemoon

Indications for Use *(Describe)*
The Bluemoon is intended to polymerize resinous dental materials, restorative composite materials, and orthodontic brackets, bonding and sealing materials that are photopolymerized in the 385~515nm waveband of visible light.

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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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

K242386

04/28/2025

1. Company

	Submitter
Name	GENOSS Co., Ltd.
Address	Head Office: 12F, 76, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Republic of Korea Manufacturing site: D-Factory, 56, Changnyong-daero 256beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, Korea
Phone/Fax	+82-70-7098-6923/ +82-31-888-5595
Contact person	Jiyeon Lee jylee3@genoss.com
Summary Date	04/28/2025

2. Device Name

Trade name:	Bluemoon
Common name:	Dental Curing Light Device
Classification name:	Ultraviolet activator for polymerization, 21 CFR 872.6070, product code EBZ, Device Class II

3. Predicate Device

K200809	D-Lux+ (Primary predicate)

4. Description

The Bluemoon Dental Curing Light is an instrument for photopolymerizing dental materials and starting agents by irradiating them with visible light between 385-515nm wavelength. It offers four modes (HYPER, TURBO, LOW, and SOFT START) depending on the output intensity and irradiation time.

5. Indication for use

The Bluemoon is intended to polymerize resinous dental materials, restorative composite materials, and orthodontic brackets, bonding and sealing materials that are photopolymerized in the 385~515nm wavelength of visible light.

6. Comparison Technological Characteristics with the Predicate Devices

Bluemoon was compared with the predicate device 'D-Lux+'. The characteristics that differed from the predicate device were performed by gap analysis, which confirmed equivalence with the predicate device. Technological characteristics of Bluemoon and D-Lux+ are as following;

Item	Proposed Device	Predicate Device K200809	Remark
Device name	Bluemoon	D-Lux+	-
Classification Regulation	21 CFR 872.6070	21 CRF 872.6070	Same
Classification	II	II	Same
Product Code	EBZ	EBZ	Same
Common Name	Activator, ultraviolet for polymerization	Activator, ultraviolet for polymerization	Same
Indications for use	The Bluemoon is intended to polymerize resinous dental materials, restorative composite materials, and orthodontic brackets, bonding and sealing materials that are photopolymerized in the 385~515nm wavelength of visible light.	The D-Lux+ is intended to polymerize resinous dental materials, restorative composite materials, and orthodontic brackets, bonding and sealing materials that are photo-polymerized in the 385~515nm waveband of visible light	Same
Use	Prescription / Hospital	Prescription / Hospital	Same
Delivery form content	- Light probe - Main body - Battery pack - Charger - Anti-glare shield - USB C to C cable - Disposable vinyl cover - User Manual	-D-Lux+ Handpiece -C-Battery -D-Lux+ Charger -Adapter -Power Cord -Disposable sheath -Light Probe -Light Protector -Instruction Manual	Gap (1)
Wavelength range	385nm - 515nm	385nm - 515nm	Same
Peak wavelength	Dual peak: 410nm, 460nm	Dual peak: 405nm, 460nm	Gap (2)
Operational modes	4 programs: -Hyper: 3s(3000mW/cm^2) -Turbo: 5s(2500mW/cm^2) -Low: 10s(1200mW/cm^2) -Soft Start: 10s(0~2000mW/cm^2)	5 modes -STD (Standard) mode: 900mW/cm2 5, 10, 15 and 20 seconds -SFT (Soft Start) mode: 1300mW/cm^2 10, 15 seconds -HIG (High Power) mode: 1300mW/cm^2 5, 10 and 15 seconds -ORT (Orthodontic) mode: 1800mW/cm^2 3, 4, 5 seconds -MAX (Max Power) mode: 2400mW/cm^2 1, 2, 3 seconds	Gap (3)
Power Source	3.7V DC with Lithium ion battery 5V DC with charger power	3.6V DC with Lithium ion battery 6V DC with charger power	Gap (4)

Light source	LED light	LED light	Same
Electrical	IEC 60601-1	IEC 60601-1	Same
Safety	IEC 60601-1- 2	IEC 60601-1-2	Same
Sterility	Non-sterile	Non-sterile	Same
Biocompatibility	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-23	Direct contact with issue in not intended. Therefore ISO 10993-1 is not applicable.	Gap (5)

6.1 Gap Analysis

Gap (1): The Main body (has a built-in battery), charger, Light probe, Anti-glare shield, adapter, Disposal vinyl cover of proposed device have the same functions with the D-Lux+ Handpiece, D-Lux+ Charger, Light Probe, Light Protector, C-Battery (Included in the handpiece), Adapter, Power Cord and Disposable Sheaths of the D-Lux+. Both devices adopt the cordless pen-style.

Gap (2): The peak wavelength values of the predecessor and application devices are very similar. The predicate device is 405, 460 nm and the proposed device is 410, 460 nm. Because the dual peak wavelengths of the two devices are so similar, they do not affect the safety or efficacy of the product.

Gap (3): The proposed device has several modes corresponding to the light output intensity and the available time. The light output safety and performance tests were performed according to IEC 60601-1, IEC 60601-1-2 and FDA guidance performance test requirements. The test results show that these differences do not affect safety and effectiveness. Therefore, it is determined that these mode differences do not cause substantial equivalence issues.

Gap (4): Both devices use the internal rechargeable lithium ion battery. Though the battery technical specification of proposed device is a bit different from that of the predicate device, the battery of proposed device meets the IEC 62133-2 standard. This difference does not affect safety and effectiveness.

Gap (5): Biocompatibility testing of the subject device was conducted because although the device does not come in contact with oral tissue on the chance that contact does occur. However, the predicate device is not evaluated. The testing results show that these differences do not affect safety and effectiveness.

7. Biocompatibility Data

Biocompatibility testing was conducted because although the device does not come in contact with oral tissue on the chance that contact does occur. The biocompatibility evaluation for the Bluemoon was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Intracutaneous reactivity test report

8. Performance Data

Bluemoon was evaluated using the following performance bench testing to confirm the performance characteristics:

No.	Title	Properties
1	Irradiation time	1) SOFT START: 10±1s 2) LOW: 10±1s 3) TURBO: 5±1s 4) HYPER: 3±1s
2	Peak wavelength	Check that the wavelength maxima occur within 5% of 400 nm and 455 nm respectively. 1) Purple: 400nm±5% 2) Blue: 455nm±5%
3	Polymerization strength measurement	≥ 80MPa
4	Depth of cure	≥ 2.0mm
5	Light Probe temperature	≤ 41℃
6	Energy-saving mode	60±2s
7	Turn off energy-saving mode	1) Buzzer sounds once, 2) LCD on
8	Auto power off	10 minutes ± 2 seconds

All test results demonstrate that the materials chosen, the manufacturing process, and the design

utilized for the Bluemoon met the established specifications necessary for consistent performance according to its intended use.

9. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.