May 12, 2025

C.E.I.B.med
% Jong-Hyun Kim
CEO
GMSC Co., Ltd.
66, Cheongcho-ro, Deogyang-gu, Goyang-si
Gyeonggi-do, 10543
Korea, South

Re: K250763
Trade/Device Name: Reon
Regulation Number: 21 CFR 872.3690
Regulation Name: Tooth Shade Resin Material
Regulatory Class: Class II
Product Code: EBF, EBG
Dated: March 12, 2025
Received: March 13, 2025

Dear Jong-Hyun Kim:

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,

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.

Submission Number *(if known)*

K250763

Device Name

Reon

Indications for Use *(Describe)*

Reon is a 3D printing resin used in dentistry for the fabrication of both temporary and permanent dental restorations, specifically crowns, bridges, inlays, onlays, and veneers.

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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Attachment U-03

510(k) Summary

K250763
510(k) Summary
[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(1)]

Mar,12, 2025

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Manufacturer: C.E.I.B.med
- Address: 1104,254,254 Beotkkot-ro, Geumchenon-gu, Seoul, Republic of Korea
- Contact Name: Kim Hyo Jeong
- Telephone No.: +82-10-4658-8705
- Email Address: hjkim@cybermed.co.kr
- Registration No.: TBD

3. Identification of Proposed Device(s) [21 CFR 807.92(a)(2)]

Trade/Device/Model Name	ReON
Common Name	Preformed Crown and Bridge
Regulation Name	Tooth shade resin material
Regulation Number	21 CFR 872.3690
Classification Product Code	EBF, EBG
Device Class	Class II
510(k) Review Panel	Dental

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate device within this submission is shown as follow;

510(k) Number	K233502
Trade/Device/Model Name	Tera Harz II
Common Name	Preformed Crown and Bridge
Regulation Name	Tooth shade resin material
Regulation Number	21 CFR 872.3690
Classification Product Code	EBF, EBG
Device Class	Class II
510(k) Review Panel	Dental

These predicate devices have not been subject to a design-related recall.

5. Description of the Device [21 CFR 807.92(a)(4)]

Reon is a photopolymerizable, methacrylate-based composite resin used in dental CAD/CAM technology for the fabrication of dental prostheses. This resin is specifically designed for both temporary and permanent dental restorations, such as crowns, bridges, inlays, onlays, and veneers, utilizing 3D printing processes.

Reon is a light-curing methacrylate-based polymer resin used in the production of dental restorations through CAD/CAM technology at dental clinics. This resin is suitable for the 3D printing process of temporary and permanent dental restorations, especially crowns, bridges, inlays, onlays, and veneers.

Reon is made from a methacrylate-based resin and is stored in liquid form in Aluminum 1050A or 1070A bottles, with two different volumes (500 g/1,000 g) for each shade. To support a variety of shades, it offers four different options: Clear, A1, A2 and A3. This resin is cured using a UV (ultraviolet) laser with a wavelength of 405nm, activated by a specific photoinitiator at 405nm.

Reon is suitable for creating custom dental restorations using UV-curing 3D printers. It can be used under the following printing and curing conditions:

Layer Thickness: 50 μm

Resolution: X, Y axis resolution of 40-90 μm

Printing Process: Compatible with DLP (Digital Light Processing) based 3D printers

Post-Curing: Final polymerization is completed by additional UV curing after printing

Reon is compatible with UV-curing 3D printers and is primarily used with the following devices:

3D Printer: DLP-based 3D printers

Software: CAD files (.stl) generated from dental software for printing

Scanner Compatibility: Intraoral Scanner and 3D design software (e.g., 3Shape)

	Brand	Type
Design:		
Intraoral scanner	Medit link	Medit i700
Design software	Asiga	Asiga composer 2.1
	Chitubox	Chitubox 1.9.5
Additive Manufacturing System:		
3D printer	Asiga	Asiga Max UV 385
	Phrozen	Phrozen Sonic mini 8K S
Post-curing:		
Post-cure unit	ODS	ODS Cure Box

The clinical workflow for Reon is as follows:

The dentist uses an intraoral scanner to scan the patient's mouth and create a CAD file.

Based on the scan data, the restoration is designed using software.

The designed STL file is used to print custom crowns, bridges, etc., with a 3D printer.

The printed restoration undergoes additional UV curing in a post-curing device to complete the hardening process.

The final restoration is then trimmed and polished to fit the patient's teeth before being provided to the patient.

Reon has passed biocompatibility testing and meets the necessary physical, chemical, and mechanical properties, making it suitable for use in dental restorations.

Please note that this product must be used in conjunction with a scanner, design software, and a 3D printer, which are not included with the product. Additionally, to achieve optimal performance, the UV curing process after printing is essential

6. Indications for Use [21 CFR 807.92(a)(5)]

Reon is a 3D printing resin used in dentistry for the fabrication of both temporary and permanent dental restorations, specifically crowns, bridges, inlays, onlays, and veneers.

7. Technological Comparison [21 CFR 807.92(a)(6)]

Provided below is a table that compares technological characteristics of the ReOn and the predicate device

[Table 3. Comparison of Proposed Device to Predicate Devices]

	Proposed Device	Predicate Device	Note
K Number		K233502	-
Manufacturer	C.E.I.B med	Graphy Inc.	-
Trade Name	ReOn	Tera Harz II	-
Product Code	EBF, EBG	EBF, EBG	Same
Regulation Number	21 CFR 872.3690	21 CFR 872.3690	Same
510(k) Review Panel	Dental	Dental	Same
Indications for Use	Reon is a 3D printing resin used in dentistry for the fabrication of both temporary and permanent dental restorations, specifically crowns, bridges, inlays, onlays, and veneers.	TERA HARZ II is indicated as an indirect restorative for both anterior and posterior restorations, including occlusal surfaces. The TERA HARZ material is used for fabricating temporary or permanent restorations such as crowns and bridges, inlays, onlays, veneers and full crown restorations. Fabrication of TERA HARZ requires a computer-aided and manufacturing (CAD/CAM) system that includes the following: scanner, design software, additive printer	Same
Mechanism of Action	The product is a photopolymer liquid resin that is manufactured to produce an output within UV lighting 3D printer. The material is for producing polymeric dental prosthesis according to ISO 10477, type 2 and class 2. Using a DLP 3D printer that uses photopolymer materials, it is produced 3D output layer by layer. By reading a STL file which contains 3D information of the dental prosthesis of a patient's oral cavity, the 3D printer can create a virtual layer to form a continuous layer. When the 3D printer	The product is a photopolymer liquid resin that is manufactured to produce an output within UV lighting 3D printer. The material is for producing polymeric dental prosthesis according to ISO 10477, type 2 and class 2. Using a DLP or SLA 3D printer that uses photopolymer materials, it is produced 3D output layer by layer. By reading a STL file which contains 3D information of the dental prosthesis of a patient's oral cavity, the 3D printer can create a virtual layer to form a continuous	Similar

	Proposed Device	Predicate Device	Note
	emits light to the resin with specific pattern of a shape, the photoinitiator in the resin absorbs the pattern of UV wavelength band. It causes a photocuring reaction in a pattern shape and the photopolymer resin is curedlayer by layer and it is continuously carried out to produce the shape that you want. The operation is carried out continuously and finally the output are produced.	layer. When the 3D printer emits light to the resin with specific pattern of a shape, the photoinitiator in the resin absorbs the pattern of UV wavelength band. It causes a photocuring reaction in a pattern shape and the photopolymer resin is curedlayer by layer and it is continuously carried out to produce the shape that you want. The operation is carried out continuously and finally the output are produced.	
Manufacturing Technology	Additive	Additive	Same
Material of Use	Methacrylate-based resins with photoinitiator, inhibitor and pigments	Methacrylate-based resins with photoinitiator, inhibitor and pigments	Similar
Product state	Pre-mixed resin(liquid)	Pre-mixed resin(liquid)	Same
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	Same
Performance Testing	ISO 10477:2020	ISO 10477:2020	Same
Depth of Cure (%) (Bottom surface shall be not less than 70% of the hardness of top surface)	Avg. 90.0	Avg. 91.3	Similar
Flexural Strength (≥50 MPa; ISO 10477)	Avg. 119.0	Avg. 125.5	Similar
Water sorption (≤40μg/mm3)	Avg. 11.0	Avg. 22.03	Similar
Solubility (≤7.5 μg/mm3)	Avg. 3.24	Avg. 0.12	Similar

	Proposed Device	Predicate Device	Note
Shade consistency	The difference in color from different bataches was not observed.	The difference in color from different bataches was not observed.	Same
Color stability	Any color change after aging treatments was not detected.	Any color change after aging treatments was not detected.	Same
OTX or Rx	Rx	Rx	Same
Sterile	non-sterile	non-sterile	Same
Shelf-life	2years	2years	Same

Based on the comparative analysis, the Proposed Device and the Predicate Device share identical intended uses, indications for use, mechanism of action, biocompatibility standards, and manufacturing technologies. While minor variations in performance metrics exist, they fall within the acceptable range of expected variability and do not raise new concerns regarding safety or effectiveness.

Furthermore, the performance testing of the Proposed Device was conducted in accordance with ISO 10477:2020, and the results confirmed compliance with the applicable acceptance criteria. As the performance data remain within the allowable limits, there are no significant safety or efficacy concerns associated with the Proposed Device.

Thus, the Proposed Device is substantially equivalent to the Predicate Device (K233502) under 21 CFR 872.3690.

In summary. there are no significant differences between the subject device and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to predicate devices in indications for use and technological characteristics.

8. Non-Clinical Test Summary

1) Biocompatibility

The 'ReON' conforms to the biocompatibility requirements established by the standards.

Standards No.	Standards Organization	Standard Title	Version	Publication Year
10993-1	ISO	Biological evaluation of medical devices – Part 1: Evaluation and testing	5.0	2018
10993-3	ISO	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	3.0	2014
10993-5	ISO	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	3.0	2009
10993-6	ISO	Biological evaluation of medical devices – Part 6: Tests for local effects after implantation	3.0	2016
10993-10	ISO	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	4.0	2021
10993-11	ISO	Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	3.0	2017

2) Manufacturing Validation

The test conducted studies on the effect of manufacturing validation and material reuse on the properties of the final finished device according to FDA's published guidance documents, "Technical Considerations for Additive Manufactured Medical Devices". The purpose of this test was to validate the performance of a 3D printer in accurately utilizing its build volume while ensuring dimensional accuracy, structural stability, and mechanical properties of printed components. Various parameters, such as build volume placement, support structures, slicing accuracy, printing quality, and environmental conditions, were assessed to optimize the printing process. The ReOn is outputted by each different output condition and each flexural strength were measured and the evaluation criteria of the all the

specimens were more than 50 MPa. In conclusion, the validation confirmed that the 3D printing system consistently produces high-quality outputs with precise dimensions and mechanical properties. The study demonstrated that optimizing build placement, support structures, slicing parameters, and environmental conditions leads to improved accuracy and reliability in additive manufacturing.

3) Reusable verification

Reon can be used multiple times from a single container. To ensure its chemical and physical stability, a validation study was conducted to assess whether the product maintains its properties despite repeated exposure to air, moisture, and contaminants during the opening and closing of the storage container. It is recommended to use the opened product within two months. Additionally, testing confirmed that the product retains its intended performance characteristics, including viscosity, curing ability, and bonding strength, even after multiple exposures throughout its usage period. This validation demonstrates that Reon continues to meet safety and performance requirements under repeated use and environmental exposure conditions.

4) Performance Testing

The predicate devices performed tests for Depth of Cure, Flexural Strength, Water Solubility, Water Sorption, and Biocompatibility content. The predicate/reference devices performed these tests as well and all met the requirements of ISO 10477:2020, Dentistry – Polymerbased crown and veneering materials.

5) Clinical data

Clinical performance data was not provided for ReOn.

9. Conclusion [21 CFR 807.92(b)(3)]

In accordance with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification, it is concluded that the 'ReOn' is substantially equivalent to the predicate device K233502.