June 4, 2025

Id Korea Co., Ltd.
Eunhui Lim
Official Correspondent
405, 150, Donggyecheon-ro
Dong-gu, Gwangju 61436
SOUTH KOREA

Re: K250804
Trade/Device Name: ID Light Cure System
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material For Resin Fillings
Regulatory Class: Class II
Product Code: EBD, EBI, EBF, MQC, KMY
Dated: March 17, 2025
Received: March 17, 2025

Dear Eunhui Lim:

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
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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)*
K250804

Device Name
ID LIGHT CURE SYSTEM

Indications for Use *(Describe)*
Crown, Bridges, Veneer, Onlay & Inlay, Denture, partial denture, Orthodontic appliance, Splints.
- Characterization of direct & indirect composite restorations, acrylic denture base and artificial acrylic teeth.
- For obtaining surface smoothness and wear resistance of restorations made of composite resin, acrylic denture base and artificial acrylic teeth.

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.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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510(k) #:

# 510(k) Summary

Prepared on: 2025-03-17

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | ID KOREA CO., LTD. |
| Applicant Address | 405, 150, Donggyecheon-ro Dong-gu Gwangju 61436 Korea, South |
| Applicant Contact Telephone | 01056887291 |
| Applicant Contact | Mrs. EUNHUI LIM |
| Applicant Contact Email | cns@cnsbest.co.kr |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | ID LIGHT CURE SYSTEM |
| Common Name | Coating material for resin fillings |
| Classification Name | Coating, Filling Material, Resin |
| Regulation Number | 872.3310 |
| Product Code(s) | EBD, EBI, EBF, MQC, KMY |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K133836 | OPTIGLAZE COLOR | EBD |

## Device Description Summary

21 CFR 807.92(a)(4)

ID LIGHT CURE SYSTEM is a light-curing resin-based coating material for dental use. It is designed to form a film on the resin surface of dental restorations and prosthetic appliances to enhance smoothness and wear resistance. The material is available in 51 shades.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Crown, Bridges, Veneer, Onlay & Inlay, Denture, partial denture, Orthodontic appliance, Splints.
- Characterization of direct and indirect composite restorations, acrylic denture base and artificial acrylic teeth.
- For obtaining surface smoothness and wear resistance of restorations made of composite resin, acrylic denture base and artificial acrylic teeth.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same between the subject and predicate device.

## Technological Comparison

21 CFR 807.92(a)(6)

It has the same technical characteristics as a predicate device.
1. Design: Materials are applied to restoration surfaces.
2. Material and chemical composition: resin-based compositions cured by photopolymerization.
3. Principle of Operation: After application, use photopolymer to irradiate light to cure the coating layer.
4. Energy source: Hardens coating agents using photopolymers that emit light of a specific wavelength.

# Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Upon evaluating the biological safety of the "**ID LIGHT CURE SYSTEM** (Model Name: CROWN FLOW A1 and 50 others)" it is considered that this product does not contain any added substances that specifically induce toxicity or have significantly different elements or mixing ratios compared to the predicate named "**OPTIGLAZE COLOR**" on the market. Furthermore, no significant differences in intended use or mechanism of action were found when compared to the predicate device. Cytotoxicity, skin sensitization, oral mucosa irritation, and acute systemic toxicity endpoint testing were performed for the subject device in accordance with ISO 10993-1:2018 and ISO 7405:2018.

Evaluation of the biological safety test reports for the "**ID LIGHT CURE SYSTEM** (Model: GUM FLOW BLACK)" showed no observed cytotoxic reactions, no oral mucosal irritation or skin sensitization reactions, and no systemic toxic reactions. Regarding additional biological safety tests for the "**ID LIGHT CURE SYSTEM** (Model Name: CROWN FLOW A1 and 50 others)," sufficient data on toxicity and benefits can be observed through the review of literature with long-term use experience.

A series of performance tests were conducted to evaluate the physical properties of the device, including appearance, weight, packaging integrity, color stability, sensitivity to ambient light, and depth of cure. All tests were performed in accordance with internal protocols and relevant standards. The device successfully passed all evaluations, demonstrating acceptable physical characteristics and confirming that the product meets its intended technical and performance specifications.

In conclusion, when the "ID LIGHT CURE SYSTEM (Model Name: CROWN FLOW A1 and 50 others)" is used according to the intended purpose and method of use provided by the manufacturer, the device is substantially equivalent to the predicate device.