March 2, 2026

Liaoning Upcera Co.,Ltd
% Jinfeng Ning
Manager
Manton Business and Technology Services
37 Winding Ridge
Oakland, New Jersey 07436

Re: K253380
Trade/Device Name: "FLNT Base" and "FLNT Temp"
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG, EBI
Dated: January 28, 2026
Received: January 28, 2026

Dear Jinfeng Ning:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253380

Please provide the device trade name(s).

"FLNT Base" and "FLNT Temp"

Please provide your Indications for Use below.

"FLNT Base" and "FLNT Temp" are used for the fabrication removable or temporary dental structures, such as crowns and bridges using milling technology using CAD/CAM.

Indications for Use:
- Temporary anterior and posterior crowns;
- Temporary anterior and posterior bridges;
- Removable structures for dentures

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (Part 21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

K253380

510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

1 Submitter & Foreign Manufacture Identification

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2 Contact Person

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3 Date of Summary: November 23, 2025

4 Device Name:

Proprietary Name:	FLNT Base
Common Name:	Removable Denture
Classification Name:	Resin, Denture, Relining, Repairing, Rebasing
Device Classification:	II
Regulation Number:	21 CFR 872.3760
Panel: General	Dental
Product Code:	EBI

Proprietary Name:	FLNT Temp
Common Name:	Temporary Crown and Bridge Resin
Classification Name:	Crown and Bridge, Temporary, Resin

Device Classification: II
Regulation Number: 21 CFR 872.3770
Panel: General Dental
Product Code: EBG

5 Predicate Device Information:

(1) K223706, "PMMA Block", manufactured by "Huliang (Shanghai) Bio-Tech Co., Ltd."

6 Device Description:

"FLNT Base" is a homogeneous polymer material composed of high-quality polymethyl methacrylate (PMMA) and cross-linking agents to improve the network structure through a unique polymerization molding technology. This material is further fabricated into a kind of temporary prosthesis, such as removable dentures. The FLNT Base is composed of PMMA and colorant. Restorations are designed and manufactured by a dental professional using CAD technology.

"FLNT Temp" is a homogeneous polymer material composed of high-quality polymethyl methacrylate (PMMA) and cross-linking agents to improve the network structure through a unique polymerization molding technology. It is indicated for manufacturing temporary crowns and bridges. Restorations are designed and manufactured by a dental professional using CAD technology.

"FLNT Base and FLNT Temp" are supplied in different shapes, such as blocks, discs, rods. It is also supplied in different colors, and single or multi-layer aesthetic effect.

7 Indications for Use:

"FLNT Base and FLNT Temp" are used for the fabrication removable or temporary dental structures, such as crowns and bridges using milling technology using CAD/CAM.

Indications for Use:
- Temporary anterior and posterior crowns;
- Temporary anterior and posterior bridges;
- Removable structures for dentures

8 Technological Comparison with Predicate Device

The following table shows similarities and differences of use, design, and material between our device and the predicate devices.

Table 5.1: Comparison of Intended Use, Design, Material, and Processing

Description	Subject Device	Predicate Device (K223706)
Indication for Use	The devices are used for the fabrication removable or temporary dental structures, such as crowns and bridges using milling technology using CAD/CAM. Indications for Use: - Temporary anterior and posterior crowns; - Temporary anterior and posterior bridges; - Removable structures for dentures	PMMA BLOCK is used for the fabrication removable or temporary dental structures, such as crowns and bridges using milling technology using CAD/CAM. Indications for Use: - Temporary anterior and posterior crowns; - Temporary anterior and posterior bridges; - Removable structures for dentures; - Removable structures for therapeutic restorations (night guards, bite splints or occlusal splints).
Basic Design	Blocks, disc, and rod	Blocks, disc, and rod
Materials	PMMA and colorants	PMMA and colorants
Processing	Polymerization	Polymerization
Dimension	Various	Various
Single Use	Yes	Yes
Shade	10 shades for “FLNT Base” 25 shades for “FLNT Temp”	Various shades
Aesthetic Effect	Single and multilayer aesthetic effect.	Information not available
Sterile	Non-sterile	Non-sterile

Our device is essentially identical to the predicate device in terms of indications for use, design, material, and processing between our device and the predicate devices. The minor differences do not raise any safety and effectiveness concerns.

9 Summary of Biocompatibility

The subject device is substantially equivalent to the predicate devices that have been legally marketed for years and with no clinical adverse events. The formulation of new device does not contain any non-conventional chemicals compared to the legally marketed predicate device.

Biocompatibility tests were performed following the current version of ISO 10993 standards. The following biocompatibility end points were evaluated:

- Cytotoxicity (ISO 10993-5)
- Irritation & Sensitization (ISO 10993-10)
- Acute Systematic Toxicity (ISO 10993-11)
- Subacute Subchronic Systematic Toxicity (ISO 10993-11)
- Material Mediated Pyrogenicity (ISO 10993-11)
- Implantation (ISO 10993-6)
- Chronic Systematic Toxicity (ISO 10993-11)
- Genotoxicity (ISO 10993-3)
- Carcinogenicity (ISO 10993-3)

10 Summary of Non-Clinical Testing:

The following table shows similarities and differences of the key performance between our device and the predicate devices.

Table 5.2: Comparison of Performance Testing

Description	Subject Device	Predicate Device (K223706)
Flexural Strength	FLNT Base > 65 PMa FLNT Temp > 50 PMa	ISO 20795 > 65 PMa ISO 10477 > 50 PMa
Water Sorption	FLNT Base $\leq$ 32 μ g/mm^3 FLNT Temp $\leq$ 40 μ g/mm^3	ISO 20795 $\leq$ 32 μ g/mm^3 ISO 10477 $\leq$ 40 μ g/mm^3
Water Solubility	FLNT Base $\leq$ 1.6 μ g/mm^3 FLNT Temp $\leq$ 7.5 μ g/mm^3	ISO 10795 $\leq$ 1.6 μ g/mm^3 ISO 10477 $\leq$ 7.5 μ g/mm^3
Residue Monomer	FLNT Temp < 2.2%	ISO 20795 < 2.2%

Tests were conducted following applicable procedures outlined in the FDA recognized consensus standard of ISO 20795 (for FLNT Base) and ISO 10477 (for FLNT Temp), and results met all relevant requirements in the test standards, and are comparable to the predicate device in performance.

11 Summary of Clinical Study:

Clinical Study is not performed for this device.

12 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that “FLNT Base and FLNT Temp” and their predicate devices have similar indications for use, similar composition, and biocompatibility, similar manufacturing process, and similar performance.

The difference between the “FLNT Base and FLNT Temp” and their predicate device do not raise any question regarding its equivalence.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, the subject device is respectively substantially equivalent to the predicate device.