February 21, 2025

Taiwan Dental Materials CO., LTD.
Pey-Fen Tang
Senior R&D Engineer
11F., No. 136, Sec. 3, Zhongxiao E. Rd., Da'an Dist.
Taipei, 106671
TAIWAN

Re: K243951
Trade/Device Name: TEMP MASTER, PMMA-based dental resin
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown And Bridge Resin
Regulatory Class: Class II
Product Code: EBG
Dated: December 23, 2024
Received: December 23, 2024

Dear Pey-Fen Tang:

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

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)*

K243951

Device Name

TEMP MASTER, PMMA-based dental resin

Indications for Use *(Describe)*

TEMP MASTER, PMMA-based dental resin developed by Taiwan Dental Materials CO., LTD. is a self-cured resin indicated for the fabrication of short-term restorations including temporary inlays, crowns, and bridges, which can protect or restore damaged teeth while permanent restorations are being prepared. It is a traditional auto-cured PMMA-based resin composed of powder and liquid. Polymerization occurs when the powder and liquid are mixed at room temperature.

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.

510(k) Summary

[TEMP MASTER, PMMA-based dental resin]

[2024/08/15]

K243951

510(k) SUMMARY

[TEMP MASTER, PMMA-based dental resin]

1. Contact Person

Company name: Taiwan Dental Materials CO., LTD.
Name: Pey Fen, Tang
Title: Senior R&D Engineer
E-mail: tangzs012304@gmail.com
Office address: 7F., No. 161, Sec. 1, Jianguo S. Rd., Da'an Dist., Taipei City 106084, Taiwan (R.O.C.)
Tel: (O) +886 2 8772 4023

2. Device Name and Classification

Product Name:	TEMP MASTER, PMMA-based dental resin
Classification Name:	Temporary crown and bridge resin.
Common or Usual Name:	Dental Material
Classification Panel:	Dental Device
Regulation Number:	872.3770
Device Class:	Class 2
Product Code:	EBG

3. Predicate Device(s)

Product Name:	K073106 Unifast III
Classification Name:	Denture Relining Repairing or Rebasing Resin Temporary crown and bridge resin.
Common or Usual Name:	Dental Material
Classification Panel:	Dental Device
Regulation Number:	872.3760, 872.3770
Device Class:	Class 2
Product Code:	EBI, EBG

4. Device Description

TEMP MASTER, PMMA-based dental resin, is a self-curing (cold-cure) material designed to fabricate temporary crowns and bridges. It consists of two components: powder and liquid. Polymerization occurs when the powder and liquid are mixed at room temperature. Classified as a Type 1 (autopolymerizable) acrylic resin according to ISO 10477 standards, TEMP MASTER, PMMA-based dental resin provides reliable performance for temporary restorations.

5. Indications for Use

TEMP MASTER, PMMA-based dental resin developed by Taiwan Dental Materials CO., LTD., is a self-cured resin indicated for the fabrication of short-term restorations including temporary inlays, crowns, and bridges, which can protect or restore damaged teeth while permanent restorations are being prepared. It is a traditional auto-cured PMMA-based resin composed of powder and liquid. Polymerization occurs when the powder and liquid are mixed at room temperature.

6. Substantial Equivalence

TEMP MASTER, PMMA-based dental resin, developed by Taiwan Dental Materials, is substantially equivalent to the predicate device, Unifast III (K073106).

The subject device, TEMP MASTER, PMMA-based dental resin and the predicate device, Unifast III (K073106), are both indicated for the fabrication of temporary inlays, crowns, and bridges. However, the predicate device also includes an additional indication for the repair of fractured dentures, which is not included in the indications for the subject device.

The substantially equivalent comparison focuses on the indications and properties under the product code EBG (Crown and Bridge, Temporary, Resin). The results of this comparison demonstrate that TEMP MASTER, PMMA-based dental resin is substantially equivalent to the predicate device, Unifast III (K073106). The expanded indication of the predicate device is not relevant to the substantial equivalence determination in this document.

Table 1 The substantially equivalent comparison

Device Description			
Specifications	**Subject Device** TEMP MASTER, PMMA-based dental resin	**Predicate Device** Unifast III	**Differences**
K number	NA	K073106	NA
Classification Product code	EBG	EBI, EBG	The predicate device also includes an additional indication for the repair of fractured dentures, which is not included in the indications for the subject device. The comparison only focuses on the properties under the product code EBG (Crown and Bridge, Temporary, Resin).
Regulation no.	872.3770	872.3770, 872.3760	
Indications for use	TEMP MASTER, PMMA-based dental resin is a self-cured resin indicated for the fabrication of short-term restorations including temporary inlays, crowns, and bridges, which can protect or restore damaged teeth while permanent restorations are being prepared. It is a traditional auto-cured PMMA-based resin composed of powder and liquid. Polymerization occurs when the powder and liquid are mixed at room temperature.	Unifast III is a self-curing acrylic reisin used for a variety of dental applications, including construction of temporary inlays, crowns and bridges and repair of fractured dentures in either pressure or paint on techniques.	
Acrylic Resin	self-curing Resin	self-curing Resin	Identical
Chemical Characterization	PMMA-based resin	PMMA-based resin	Identical

Physical Properties		
ISO 10477	**Subject Device** TEMP MASTER, PMMA-based dental resin	**Predicate Device** Unifast III K073106
Flexural Strength	>50 MPa	>50 MPa
Water Absorption	Complies with ISO 10477	Complies with ISO 10477
Water Solubility	Complies with ISO 10477	Complies with ISO 10477

7. Performance Data

Biocompatibility Testing

The biocompatibility evaluation for TEMP MASTER, PMMA-based dental resin was conducted in accordance with the FDA Blue Book Memorandum #G95 and international Standard ISO 10993.

Bench Testing

- ISO 10477. Dentistry–Polymer-based crown and bridge materials. 2018.

The nonclinical tests conducted in accordance with ISO 10477 assessed the flexural strength, water sorption, and water solubility of the temporary crown and bridge dental resin. The performance characteristics of TEMP MASTER, PMMA-based dental resin, were compared to those of the predicate device, and both materials demonstrated results within the acceptable ranges defined by the standard.

Sterility and Shelf-life

The device is provided non- sterile.
From the shelf-life testing, TEMP MASTER, PMMA-based dental resin has a shelf life of 2.5 years. The shelf testing has been conducted with the bench test fromthe ISO Standard 10477 and ISO 868.

8. Similarity and differences

TEMP MASTER, PMMA-based dental resin is similar to the predicate device in the method of processing. The main difference is the slight differences in the percentage of chemical composition. The chemical composition might influence the biocompatibility of TEMP MASTER, as well as its performance (mechanical properties). Thus, both biocompatibility and performance has been demonstrated for TEMP MASTER. The same tests according to the same standards ISO 10993 and ISO 10477 were used to show biocompatibility and performance of the predicate.

9. Conclusion

After analyzing bench test, device description and intended use/ indication for use, it can be concluded that TEMP MASTER, PMMA-based dental resin is as safe and effective as the predicate device, Unifast III (K073106).