



April 6, 2026

YAMAHACHI DENTAL MFG., Co.
Hirota Shuhei
Quality Control Section
54-1 Ochigara, Nishiura-Cho
Gamagori, Aichi 443-0105
JAPAN

Re: K254091
Trade/Device Name: Glossy Coat (15ml)
Regulation Number: 21 CFR 872.3310
Regulation Name: Coating Material For Resin Fillings
Regulatory Class: Class II
Product Code: EBD
Dated: March 10, 2026
Received: March 11, 2026

Dear Hirota Shuhei:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

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

Indications for Use

510(k) Number (if known)
K254091

Device Name
GLOSSY COAT (15ML)

Indications for Use (Describe)

GLOSSY COAT is indicated for use in the oral cavity or on a working model to coat the surface of resin-based dental prostheses (e.g., crowns, bridges, and dentures) in order to improve surface smoothness and wear resistance.

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.

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510(k) Summary

Prepared on 2026.3.6

Contact details

Applicant name	YAMAHACHI DENTAL MFG., Co.
Applicant Address	54-1 Ochigara, Nishiura-Cho Gamagori Aichi-Pref 443-0105 Japan
Applicant Contact Telephone	+81-533-57-7121
Applicant Contact	Shuhei Hirota
Applicant Contact Email	hirota@yamahachi-dental.co.jp

Device name

	Trade Name	Model
Device Trade Name	GLOSSY COAT	15ML

Common Name: Coating material for resin fillings

Classification Name: COATING, FILLING MATERIAL, RESIN

Regulation Number: 872.3310

Product Code: EBD

Legally Marketed Predicate Device

Predicate #	Predicate Trade Name	Product Code
K133836	OPTIGLAZE COLOR	EBD



1. Device Description Summary

GLOSSY COAT is coating material. The coating material is applied to resin-based dental prostheses (e.g. crowns, bridges, and dentures) and light-cured, making it easier to achieve a glossy finish than with conventional polishing.

2. Indications for Use

GLOSSY COAT is indicated for use in the oral cavity or on a working model to coat the surface of resin-based dental prostheses (e.g., crowns, bridges, and dentures) in order to improve surface smoothness and wear resistance.

3. Technological Comparison

	Subject Device	Predicate Device	Differences	
Device Name	GLOSSY COAT	OPTIGLAZE COLOR		
Company	Yamahachi Dental	GC AMERICA INC.		
Classification & Product Code	872.3310; EBD	872.3310; EBD	Same	
Device Description	A light-cured, surface gloss coating material for restorations.	A light cured glazing and characterizing material for such restorations as direct and indirect composite resins & acrylics	Similar	The intended use of GLOSSY COAT is included in the intended use of OPTIGLAZE COLOR.
Intended Use	Apply to resin-based dental prostheses (e.g. crowns, bridges, dentures) to enhance smoothness and wear resistance	For characterization of restorations made of composite resins & acrylics. For obtaining surface smoothness and wear resistance of made of composite resins & acrylics.	Similar	The intended use of GLOSSY COAT is included in the intended use of OPTIGLAZE COLOR.
Product State	Liquid	Liquid	Same	
Recommended Curing Light Unit	LED light source Chairside LED light source	LED Light, Halogen light, Plasma Arc	Similar	Both are cured by LED light.
Effective Wavelength	365~410nm	Lower than 430nm (LED light source)	Similar	Both are cured by visible light.



Curing Time	3 min (LED light source) 20Sec (Chairside LED light source)	90 sec (GC LABOLIGHT DUO) 5 min (GC LABOLIGHT LV-III,II) 10~20 sec(GC STEPLIGHT SL-I) 40 sec (Halogen Light) 8 sec (Plasma Arc) 40 sec(LED Light (wavelength 400~430nm))	Similar	This varies greatly depending on the type of photopolymerization device.
Components	Multi-functional acrylate, Methylmethacrylate, Silica filler, Photo initiator, others	Multifunctional acrylate, Methyl methacrylate, Silica filler, Photo initiator, Pigment	Similar	The main ingredients are the same. Since it is a product of another company, it is not possible to know whether it is made of exactly the same materials.
Appearance	The cured coating surface is uniform and free of impurities	The cured coating surface is uniform and free of impurities	Similar	These are within specification (in-house standard). Therefore, the physical properties of these products are similar.
Hardness (Hv0.2) (Min: 18Hv0.2)	Above standard value	Above standard value	Similar	
Coating properties	Good	Good	Similar	
Viscosity (mPa · s) (If it is between 7 and 25, there will be no problems with operability.)	Within standard value	Within standard value	Similar	

4. Non-Clinical and/or Clinical Tests Summary & Conclusions

The hardness and viscosity of the target device and the predicate device are equivalent, and both meet the company's internal standards.

5. Substantial Equivalence Summary / Conclusion

In summary, GLOSSY COAT has the same intended use as the equivalent product. The method to fabricate the final product and the physical properties are also almost the same as the equivalent product. The equivalent product is a product of another company, so the detailed ingredients are unknown, but the main ingredients are also the same as the equivalent product. In conclusion, GLOSSY COAT has been proven to be legally substantially equivalent to the commercially available device OPTIGLAZE COLOR (K133836) and has received appropriate approval for pre-marketing activities in the United States.



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6. Test of Biocompatibility Summary & Conclusions

The category and contact parts of GLOSSY COAT are as follows according to ISO 10993-1:2025.

Category: Surface device

Contact parts: Mucosal membrane (oral cavity) Duration: Long term (more than 30 days)

The product was evaluated for the following items in accordance with ISO 10993-1:2025 and demonstrated its biological safety.

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Local effects
- Genotoxicity
- Carcinogenicity