July 22, 2025

ODS Co., Ltd.
% Kyung-Hwan Kim
Representative Consultant, RA/QA
SMB Korea Co.
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Seoul, 07071
SOUTH KOREA

Re: K251616
Trade/Device Name: Clear Miracle
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: May 21, 2025
Received: May 27, 2025

Dear Kyung-Hwan 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,

MICHAEL E. ADJODHA -S

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Assistant Director
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K251616

Device Name
Clear Miracle

Indications for Use *(Describe)*
Clear Miracle is a clear orthodontic appliance designed to treat malocclusions in patients with permanent dentition (i.e., all second molars). It uses a series of gradual tooth movements to position teeth sequentially with continuous gentle force. Clear Miracle is intended for professional use only.
To fabricate an aligner with Clear Miracle, an Additive Manufacturing System (AMS) compatible with the following is required:

	Brand	Type
Design:		
Intraoral scanner	3Shape	Trios 3
Design software	3Shape	3Shape Ortho System
Additive Manufacturing System:		
3D Printer	Phrozen	Sonic Mini 8K
Post-Curing:		
Post-cure unit	Cubicon	ODS Cure Box V3

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
For
Clear Miracle

Prepared in Accordance with 21 CFR 807.92

I. Submitter Information

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Date Prepared: May 30, 2025

II. Device Information

Trade or Proprietary Name:	Clear Miracle
Common or Usual Name:	Sequential Aligner
Classification Name:	Orthodontic plastic bracket (21 CFR 872.5470)
Regulatory Class:	Class II
Product Code:	NXC
Classification Panel:	Dental

III. Predicate Device

Device Name:	TERA HARZ CLEAR (K223355)
Manufacturer:	Graphy Inc.
Product Code:	NXC
Classification:	Class II (21 CFR 872.5470)

IV. Device Description

Clear Miracle is a methacrylate-based resin designed for creating clear, light-cured aligners. It is supplied in 250-gram bottles made of high-density polyethylene (HDPE) and is a light yellow in color. Exposure to ultraviolet (UV) light within the 405–412-nanometer

(nm) wavelength range causes the liquid resin to solidify into a three-dimensional structure. The resin contains a photoinitiator that begins the curing process at wavelengths between 405 and 412 nm. During additive manufacturing, Clear Miracle forms 50-µm-thick layers, achieving a resolution of 0.022 mm in the X and Y axes. This ensures the creation of high-precision orthodontic aligners through a layer-by-layer curing process.

V. Indications for Use

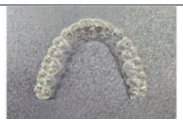
Clear Miracle is a clear orthodontic appliance designed to treat malocclusions in patients with permanent dentition (i.e., all second molars). It uses a series of gradual tooth movements to position teeth sequentially with continuous gentle force. Clear Miracle is intended for professional use only.

To fabricate an aligner with Clear Miracle, an Additive Manufacturing System (AMS) compatible with the following is required:

	Brand	**Type**
Design:		
Intraoral scanner	3Shape	Trios 3
Design software	3Shape	3Shape Ortho System
Additive Manufacturing System:		
3D Printer	Phrozen	Mini 8K
Post-Curing:		
Post-cure unit	ODS Co., Ltd.	ODS Cure Box V3

VI. Technological Characteristics Comparison

	SUBJECT Device	**PREDICATED Device (K223355)**	**Significant Difference**
Manufacturer	**ODS Co., Ltd.**	**Graphy Inc.**	–
Trade Name	Clear Miracle	TERA HARZ CLEAR	–
Regulation Description	Orthodontic plastic bracket	Orthodontic plastic bracket	No difference.
Regulation Number	21 CFR 872.5470	21 CFR 872.5470	No difference.
Product Code	NXC	NXC	No difference.
Class	II	II	No difference.
Indications for Use	Clear Miracle is a clear orthodontic appliance designed to treat malocclusions in patients with permanent dentition (i.e., all second molars). It uses a series of gradual tooth movements to position teeth sequentially with continuous gentle force. Clear Miracle is intended for	TERA HARZ CLEAR is intended for the treatment of tooth malocclusions in patients with permanent dentition (i.e., all second molars). Utilizing a series of incremental tooth movements, it sequentially positions teeth by way of continuous gentle force. TERA HARZ CLEAR is intended	No difference.

	SUBJECT Device	PREDICATED Device (K223355)	Significant Difference
	professional use only.	exclusively for professional dental work.	
Design			Similarities: The arch shape does not introduce any additional safety or efficacy concerns.
Mechanism of Action	Orthodontic tooth movement occurs when an appliance applies force to the teeth. Then, each tooth moves according to a predetermined plan based on the orthodontist's instructions.	Orthodontic tooth movement occurs through forces applied to the teeth by the appliance to the dentition as each tooth follows the programmed displacement based on a dental health professional's prescription.	No difference.
In Use Duration	The aligners are worn for about one week, 20 to 22 hours per day, and then replaced with the next set. This process continues as prescribed by the orthodontist.	Aligners are worn for approximately 1 week of 20-22 hours of wear per day, after which itis replaced by the next stage aligners. This is repeated for duration as prescribed by the dental clinician.	No difference.
Materials of Use	Methacrylate-based resins	Methacrylate-based resins	No difference.
Manufacturing Technology	Additive	Additive	No difference.
Performance Testing	ISO 20795-2:2013	ISO 20795-2:2013	No difference.
Polishability	The specimen plates had present a smooth surface with a high gloss.	The specimen plates had present a smooth surface with a high gloss.	No difference.
Color	The color matched.	The color matched.	No difference.
Freedom from porosity	There was no porosity.	There was no porosity.	No difference.
Ultimate Flexural Strength (≥50 MPa)	Min. 99 to Max. 105	Min. 62 to Max. 67	Difference
Flexural modulus (≥1500 MPa)	Min. 1,629 to Max. 1924	Min. 1,545 to Max. 1,595	Difference
Residual methyl methacrylate monomer	0%	0%	No difference.
Solubility (≤5 μg/mm³)	Min. 0 to Max. 1.0	Min. 1.5 to Max. 2.1	Difference
Water sorption	Min. 14.0 to Max. 17.0	Min. 13.0 to Max. 14.8	Difference

	SUBJECT Device	PREDICATED Device (K223355)	Significant Difference
(≤32 μg/mm³)			
Biocompatibility	Biocompatible according to ISO 10993-1	Biocompatible according to ISO 10993-1	No difference.
OTC or Rx	Rx only	Rx only	No difference.
Sterile	Not Applicable	Not Applicable	No difference.
Shelf-life	2 years	2 years	No difference.

VII. Performance Data

1. Non-Clinical Testing

The following performance data was provided in support of the substantial equivalence determination.

- **Biocompatibility**

  Biocompatibility classification follows FDA Guidance and ISO 10993-1 standards. Devices are classified as surface-contacting with long-term mucosal membrane exposure (>30 days). They meet requirements outlined in ISO 7405:2018 for dental devices, ISO 10993-1:2018, and FDA guidance for biological evaluation. Testing includes cytotoxicity (ISO 10993-5), irritation (ISO 10993-10/23), and implantation (ISO 10993-6), confirming substantial equivalence to predicate device K223355.

- **Mechanical Properties**

  Tests were conducted on the Clear Miracle in compliance with ISO 20795-2:2013, Dentistry – Base Polymers – Part 2: Orthodontic Base Polymers, to confirm substantial equivalence in safety and efficacy compared to the predicate device. These tests included evaluations of appearance, weight, surface characteristics, color, porosity, residual methyl methacrylate monomer content, ultimate flexural strength, flexural modulus, water sorption, and water solubility.

- **Additive Manufacturing Process Validation**

  ODS Co., Ltd. completed validation of Clear Miracle photocurable resin for 3D-printed orthodontic aligners, meeting ISO 20795-2 standards and FDA guidelines. Tests evaluated post-cure optimization, print parameters, dimensional accuracy, and resin reusability. Measurements showed dimensional accuracy within ±0.150 mm and mechanical properties exceeding requirements (50 MPa flexural strength, 1,500 MPa modulus). Optimal parameters include 0° exit angle and centered positioning. Clear Miracle resin remained effective through seven consecutive print cycles, confirming process reliability.

2. Clinical Testing

Clinical performance data were not required due to substantial equivalence to the predicate device.

VIII. Substantial Equivalence Conclusion

The Clear Miracle demonstrates substantial equivalence to the predicate device TERA HARZ CLEAR (K223355) through identical material composition, manufacturing processes, and intended use; superior flexural strength while meeting ISO 20795-2 and biocompatibility standards; and the absence of any new risks identified compared to the predicate.