

Graphy Secures FDA Clearance for Denture Materials, Targeting the \$40 Billion market

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MIAMI, FL, UNITED STATES, December 3, 2025 /EINPresswire.com/ -- [Graphy](#) Secures FDA Clearance for Denture Materials, Targeting the \$40 Billion market

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- FDA 510(k) clearance for eight TERA HARZ Hard Denture series materials paves the way for full-scale expansion in the North American prosthetic materials market

- Leveraging the world's first SMA-based technology to extend its 3D printing materials portfolio across orthodontics, prosthetics, dentures, and sports guards

- Graphy holds 58 FDA 510(k) clearances and 37 CE certifications for 3D printing dental materials, representing a top-tier global regulatory track record among Korean 3D printing companies

South Korean company Graphy Inc. (KOSDAQ: 318060, CEO Unseob Sim), a specialist in 3D-printing-based [Shape Memory Aligner](#) (SMA) solutions, has received U.S. Food and Drug



Corporate and brand identities of Graphy and the world's first direct 3D-printable Shape Memory Aligner® — a game-changer in digital orthodontics.



A researcher at Graphy's Corporate Research Institute performs material analysis, demonstrating the company's scientific rigor in developing advanced 3D-printing dental resins.

Administration (FDA) 510(k) clearance for its TERA HARZ Hard Denture [dental resin](#) series for 3D printers, accelerating the company's advance into the rapidly growing global prosthetic materials market, estimated at approximately USD 40 billion in annual consumer spending.

According to the FDA's official database, the latest clearance covers eight models within Graphy's TERA HARZ Hard Denture lineup: THD-C-500, THD-C-1000, THD-LP-500, THD-LP-1000, THD-P-500, THD-P-1000, THD-CP-500, and THD-CP-1000. The series is based on Graphy's proprietary polymer and oligomer synthesis technologies and is engineered to deliver high mechanical strength, appropriate flexibility, and long-term durability, making it particularly suitable for 3D-printed dentures. Building on this, Graphy had already secured U.S. FDA 510(k) clearances for permanent crown-and-bridge resins (TC-80, BR-23), Shape Memory Aligner resins (TC-85, TA-28, TR-07), an implant surgical guide resin (SG-100), a flexible denture resin (TFDH), and a mouthguard material (TE-151), enabling the company to address virtually the full spectrum of 3D printed dental material indications.

Graphy's Corporate Research Institute is the R&D organization behind the world's first 3D-printed Shape Memory Aligner and has since expanded the company's materials platform across orthodontics, prosthetics, dentures, and sports guards. With the newly cleared TERA HARZ Hard Denture series, Graphy now holds 58 FDA 510(k) clearances and 37 CE certifications specifically for 3D printing dental materials—one of the strongest global regulatory track records among Korean 3D printing companies. These approvals underpin the rapid expansion of Graphy's core materials,



Researchers at Graphy's Corporate Research Institute conduct material testing and workflow validation, supporting the company's nationally recognized R&D excellence.

What makes Graphy material different?
The world's best flexible material. (MFDS Class2, FDA Class2, CE Class2)
Fast, accurate, and highly satisfactory 3D-printed dental devices.

Introduction of Products

Shape Memory Aligners (Tera Harz Clear)	Permanent C&B (TC-80DP, BR-23)	Flexible Denture (TFDH)
All-on-X (R-191 + THD)	Surgical Guide (SG-100)	Dental Model (S-100M, S-200M)

Graphy's cutting-edge orthodontic solution

3D Printer Formlabs 4B	Curing Machine Tera Harz Cure	Spinner Tera Harz Spinner
Self Care Tera Harz Care	Face Scanner Ray Face	Intraoral Scanner Comfort +

Shape Memory Aligner® Graphy
3D Print the World with Graphy's Solutions

Graphy's Cutting-Edge Digital Dental Solutions

SMA Production process

1. Scan → 2. Design(Setup) → 3. 3D Printing → 4. SMA Complete

Tera Harz Clear Resin

Tera Harz Smart Robot

All processes in one seamless operation by Robotic technology

- Technical excellence and competitiveness
- Improvement outcomes
- Economic benefits
- Time efficiency

Graphy Teams

All-in-One System for seamless Order Placement, Treatment Planning, and Production Management

Dental Workflow

1. Intraoral Scanning → 2. Online order & Treatment Plan Approval → 3. SMARTCheck : Digital Scan & Treatment Planning

SMARTCheck : Digital Scan & Treatment Planning

- Patient data is uploaded to the SMARTCheck system to generate a customized treatment plan for each case.
- The proposed plan can be reviewed, modified, and approved via SMARTCheck Viewer. Once approved, treatment proceeds based on the approved plan.

Shape Memory Aligner® Graphy
3D Print the World with Graphy's Solutions

Flexible User Options: One-Click Order or In-House Production

which are already supplied to more than 100 countries across North America, Europe, the Middle East, and Asia.

A Graphy spokesperson commented, “The materials that received FDA clearance this time are denture resins designed for digital 3D printing. By enabling dental laboratories to transition from conventional hand-crafted dentures to fully digital workflows, they are expected to significantly improve productivity and precision.” The spokesperson added, “We continue to obtain FDA clearances for a broad range of 3D printing dental resins, including shape-memory aligner resins, mouthguard materials, and tooth-colored restorative and shading materials. These regulatory milestones will further accelerate our sales and partnership expansion in North America on the strength of U.S. FDA approval.”

Leveraging its oligomer-synthesis-based, customized 3D printing material development capabilities, Graphy became the first company in the world to commercialize Shape Memory Aligner clear aligners. Rather than simply supplying materials, the company provides an integrated solution that combines 3D printers, dedicated software, and validated production protocols, helping dental clinics and laboratories meet the growing demand for digital workflows.

Graphy’s shape memory clear aligner is a next-generation orthodontic device engineered to address the limitations of conventional thermoformed clear aligners, such as cracking, deformation, and the loss of orthodontic force over time. Clinical cases and peer-reviewed studies have demonstrated the technology’s performance and treatment efficiency. The global orthodontics market is projected to grow from approximately USD 70 billion in 2023 to around USD 110 billion by 2030, with North America accounting for roughly 45% of total demand. Industry observers note that, because FDA 510(k) clearance is widely recognized as a key benchmark for the safety and quality of medical devices, this latest approval further validates the competitiveness of Korean 3D printing dental materials technology on the global stage.

Looking ahead, Graphy plans to increase its market share by expanding its distribution network in the United States, strengthening partnerships with dental clinics, hospitals, and laboratories, and deepening collaboration with global manufacturers. A company representative stated, “By leveraging 3D printing dental materials and shape memory clear aligner solutions that meet global standards, we will further elevate the presence of Korean companies in the global market.”

Graphy is also accelerating its global outreach through a series of major international events. In October, the company generated strong response with an encore lecture session—attended by more than 1,500 participants—on Shape Memory Aligner clinical cases at the International Orthodontic Congress (IOC) in Rio de Janeiro, Brazil. This will be followed by the Taiwan Association of Orthodontists (TAO) annual meeting in Tainan, Taiwan (December 6–7), DWDM 2026 (January 18) and AEEDC 2026 (January 19–21) in Dubai, United Arab Emirates, and LMT Lab Day (February 19–21) and the Chicago Dental Society (CDS) Meeting (February 19–21) in Chicago,

United States. Across these venues, Graphy will actively promote its Shape Memory Aligner technology and 3D printing dental and medical material platforms while securing new global partners and strengthening its overseas sales pipeline.

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