

**K240597 TERA HARZ CLEAR**Mar 5, 2024  
1 days to decisionK240597 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k240597/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Aligner, Sequential (NXC)
Date received	Mar 4, 2024
Decision date	Mar 5, 2024
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Graphy, Inc.</b>
Location	Seoul, KR
Contact	Moon-Soo Park
510(k) history	6 submissions · 6 cleared · 2021-2025

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Third Party Review Group, LLC</b>
Contact	Dave Yungvirt

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240597/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026