

**K222414 TERA HARZ DENTURE**Aug 11, 2022  
1 days to decisionK222414 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k222414/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Resin, Denture, Relining, Repairing, Rebasing (EBI)
Date received	Aug 10, 2022
Decision date	Aug 11, 2022
Days to decision	1 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222414/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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