

**K253681 TERA HARZ Hard Denture (THD-C-500)**

Nov 21, 2025

K253681 · Product code: **EBI** · DentalSource: <https://www.510kdatabase.net/k253681/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)   |
| Submission type       | Traditional  |
| Device classification | Resin, Denture, Relining, Repairing, Rebasing (EBI)  |
| Date received         | Nov 21, 2025   |
| Decision date         | Nov 21, 2025   |
| Third-party review    | Yes  |
| Combination product   | No   |
| PCCP authorized       | No   |
| Summary / Statement   | Summary  |
| Other names           | TERA HARZ Hard Denture (THD-C-1000); TERA HARZ Hard Denture (THD-LP-500); TERA HARZ Hard Denture (THD-LP-1000); TERA HARZ Hard Denture (THD-P-500); TERA HARZ Hard Denture (THD-P-1000); TERA HARZ Hard Denture (THD-CP-500); TERA HARZ Hard Denture (THD-CP-1000) |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Graphy, Inc.</b>                   |
| Location       | Seoul, KR                             |
| Contact        | Moon-Soo Park                         |
| 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](https://accessdata.fda.gov)

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