

**K223355 Tera Harz Clear**Nov 3, 2022  
1 days to decisionK223355 · Product code: **NXC** · Dental  
Source: <https://www.510kdatabase.net/k223355/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Aligner, Sequential (NXC)          |
| Date received         | Nov 2, 2022                        |
| Decision date         | Nov 3, 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        | Moon Soo Part                         |
| 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/k223355/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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