

**K202846 TERA HARZ**Jul 15, 2021  
293 days to decisionK202846 · Product code: **EBF** · Dental  
Source: <https://www.510kdatabase.net/k202846/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Material, Tooth Shade, Resin (EBF)
Date received	Sep 25, 2020
Decision date	Jul 15, 2021
Days to decision	293 days
Third-party review	No
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>Plusglobal</b>
Contact	Peter Chung

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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