FDA 510(k) Premarket Notification

**CLEARED**

# K250393 ZircaGlow & ZircaGlow HT Zirconia

May 12, 2025
89 days to decision

K250393 · Product code: **EIH** · Dental
Source: https://www.510kdatabase.net/k250393/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powder, Porcelain (EIH) |
| Date received | Feb 12, 2025 |
| Decision date | May 12, 2025 |
| Days to decision | 89 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **United Zirconia** |
| Location | Cairo, EG |
| Contact | Kanal Ebeid |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **T² & Company** |
| Contact | Tim Torbenson |

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