

**K241316 Zirconia Block**Jul 9, 2024  
60 days to decisionK241316 · Product code: **EIH** · Dental  
Source: <https://www.510kdatabase.net/k241316/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Powder, Porcelain (EIH)            |
| Date received         | May 10, 2024                       |
| Decision date         | Jul 9, 2024                        |
| Days to decision      | 60 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Hunan Hualian Special Ceramics Co., Ltd.</b> |
| Location       | Liling, CN                                      |
| Contact        | Fusheng Chen                                    |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024           |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241316/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 13, 2026