

**K160079 rainbow Shine**Nov 10, 2016  
301 days to decisionK160079 · Product code: **EIH** · DentalSource: <https://www.510kdatabase.net/k160079/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Powder, Porcelain (EIH)            |
| Date received         | Jan 14, 2016                       |
| Decision date         | Nov 10, 2016                       |
| Days to decision      | 301 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Genoss Co., Ltd.</b>                 |
| Location       | Laguna Niguel, CA, US                   |
| Contact        | Byungsun Kim                            |
| 510(k) history | 18 submissions · 18 cleared · 2007-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160079/> 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 25, 2026