

**K131212 PREMIER CERAMIC PRIMER**Aug 26, 2013  
119 days to decisionK131212 · Product code: **KLE** · Dental  
Source: <https://www.510kdatabase.net/k131212/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Agent, Tooth Bonding, Resin (KLE)  |
| Date received         | Apr 29, 2013                       |
| Decision date         | Aug 26, 2013                       |
| Days to decision      | 119 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Premier Dental Products Co.</b>      |
| Location       | Mchenry, IL, US                         |
| Contact        | VINCENT D&apos;ALESSANDRO               |
| 510(k) history | 41 submissions · 41 cleared · 1977-2014 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131212/> 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 June 5, 2026