

**K192961 ADH19**Oct 31, 2019  
9 days to decisionK192961 · Product code: **KLE** · Dental  
Source: <https://www.510kdatabase.net/k192961/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Agent, Tooth Bonding, Resin (KLE)  |
| Date received         | Oct 22, 2019                       |
| Decision date         | Oct 31, 2019                       |
| Days to decision      | 9 days                             |
| Third-party review    | Yes                                |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|                |   |
|----------------|---|
| Company        | <b>3M Deutschland GmbH</b>              |
| Location       | Bavaria D-82228 Seefeld, DE             |
| Contact        | Ruediger Franke                         |
| 510(k) history | 12 submissions · 12 cleared · 2012-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192961/> 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 27, 2026