

K161077 RnD TE and RnD SEMar 17, 2017
333 days to decisionK161077 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k161077/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Agent, Tooth Bonding, Resin (KLE) |
| Date received | Apr 18, 2016 |
| Decision date | Mar 17, 2017 |
| Days to decision | 333 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Apex Dental Materials, Inc. |
| Location | Schaumburg, IL, US |
| Contact | Scott Lamerand |
| 510(k) history | 15 submissions · 15 cleared · 2001-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161077/> Data sourced from FDA 510(k) public records (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. - Generated June 18, 2026