

K974283 PQ 1Jan 29, 1998
76 days to decisionK974283 · Product code: **KLE** · DentalSource: <https://www.510kdatabase.net/k974283/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Agent, Tooth Bonding, Resin (KLE) |
| Date received | Nov 14, 1997 |
| Decision date | Jan 29, 1998 |
| Days to decision | 76 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Ultradent Products, Inc. |
| Location | Salt Lake City, UT, US |
| Contact | CHESTER MCCOY |
| Website | https://www.ultradent.com |
| 510(k) history | 103 submissions · 103 cleared · 1992-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k974283/> 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 28, 2026