

K942017 V-PRIMERJul 6, 1994
71 days to decisionK942017 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k942017/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Agent, Tooth Bonding, Resin (KLE) |
| Date received | Apr 26, 1994 |
| Decision date | Jul 6, 1994 |
| Days to decision | 71 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Parkell, Inc. |
| Location | Mchenry, IL, US |
| Contact | NELSON J GENDUSA |
| 510(k) history | 53 submissions · 53 cleared · 1976-2025 |

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