

K112597 SEITY 37% PHOSPHORIC ACID ETCHANT GELDec 7, 2011
91 days to decisionK112597 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k112597/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Agent, Tooth Bonding, Resin (KLE) |
| Date received | Sep 7, 2011 |
| Decision date | Dec 7, 2011 |
| Days to decision | 91 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Mycone Dental Supply Co., Inc. |
| Location | Cherry Hill, NJ, US |
| Contact | WILLIAM EVANS |
| 510(k) history | 3 submissions · 3 cleared · 2003-2011 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k112597/> 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 15, 2026