

K161051 All-Bond Universal w/BAC (not finalized)Sep 9, 2016
148 days to decisionK161051 · Product code: **KLE** · Dental
Source: <https://www.510kdatabase.net/k161051/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Agent, Tooth Bonding, Resin (KLE) |
| Date received | Apr 14, 2016 |
| Decision date | Sep 9, 2016 |
| Days to decision | 148 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Bisco, Inc. |
| Location | Mchenry, IL, US |
| Contact | Ryan Hobson |
| 510(k) history | 88 submissions · 88 cleared · 1984-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161051/> 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 May 14, 2026