

K150492 Ora-GUARD Dental Grind GuardFeb 19, 2016
359 days to decisionK150492 · Product code: **OBR** · Dental
Source: <https://www.510kdatabase.net/k150492/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mouthguard, Over-the-counter (OBR) |
| Date received | Feb 25, 2015 |
| Decision date | Feb 19, 2016 |
| Days to decision | 359 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bite Tech, Inc. |
| Location | Norwalk, CT, US |
| Contact | Jeff Padovan |
| 510(k) history | 1 submissions · 1 cleared · 2016-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150492/> 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 3, 2026