

K240810 Anti Grinding GuardMay 24, 2024
60 days to decisionK240810 · Product code: **OBR** · Dental
Source: <https://www.510kdatabase.net/k240810/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mouthguard, Over-the-counter (OBR) |
| Date received | Mar 25, 2024 |
| Decision date | May 24, 2024 |
| Days to decision | 60 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Xiamen Yizhou Imp. & Exp. Co., Ltd. |
| Location | Xiamen, CN |
| Contact | Elaine Huang |
| 510(k) history | 1 submissions · 1 cleared · 2024-2024 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Shanghai SUNGO Management Consulting Co., Ltd. |
| Contact | Ivy Wang |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240810/> 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 13, 2026