

**K211069 EndSnorZ Sleep Appliance**Oct 26, 2021  
197 days to decisionK211069 · Product code: **LRK** · Dental  
Source: <https://www.510kdatabase.net/k211069/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Device, Anti-snoring (LRK)         |
| Date received         | Apr 12, 2021                       |
| Decision date         | Oct 26, 2021                       |
| Days to decision      | 197 days                           |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Prismatik Dentalcraft, Inc.</b>      |
| Location       | Newport Beach, CA, US                   |
| Contact        | Herbert Schoenhoefer                    |
| 510(k) history | 57 submissions · 57 cleared · 2010-2026 |

**REGULATORY CONSULTANT**

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|-----------------|-------------------------------|
| Consulting firm | <b>Qserve Group, Us, Inc.</b> |
| Contact         | Patsy J Trisler               |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA [accessdata.fda.gov](https://accessdata.fda.gov)

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