

K190058 PureSleep (OTC use)Apr 11, 2019
90 days to decisionK190058 · Product code: **LRK** · Dental
Source: <https://www.510kdatabase.net/k190058/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Anti-snoring (LRK) |
| Date received | Jan 11, 2019 |
| Decision date | Apr 11, 2019 |
| Days to decision | 90 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Sleep Science Partners, Inc. |
| Location | Larkspur, CA, US |
| Contact | Noel P. Lindsay |
| 510(k) history | 2 submissions · 2 cleared · 2012-2019 |

REGULATORY CONSULTANT

| | |
|-----------------|----------------------|
| Consulting firm | leanRAQA, LLC |
| Contact | Valerie Followell |

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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