

**K222262 Sunrise**Dec 22, 2022  
147 days to decisionK222262 · Product code: **QRS** · Anesthesiology  
Source: <https://www.510kdatabase.net/k222262/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                |
| Submission type       | Traditional   |
| Device classification | Device For Sleep Apnea Testing Based On Mandibular Movement (QRS) |
| Date received         | Jul 28, 2022  |
| Decision date         | Dec 22, 2022  |
| Days to decision      | 147 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Sunrise SA</b>                     |
| Location       | Namur, BE                             |
| Contact        | Gregoire Lejeune                      |
| 510(k) history | 2 submissions · 2 cleared · 2022-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222262/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 26, 2026