

K250874 SunriseAug 29, 2025
158 days to decisionK250874 · Product code: **QRS** · AnesthesiologySource: <https://www.510kdatabase.net/k250874/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device For Sleep Apnea Testing Based On Mandibular Movement (QRS)
Date received	Mar 24, 2025
Decision date	Aug 29, 2025
Days to decision	158 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sunrise SA
Location	Namur, BE
Contact	Grégoire Lejeune
510(k) history	2 submissions · 2 cleared · 2022-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250874/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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