

K223573 Onera Sleep Test System (Onera STS)Aug 18, 2023
261 days to decisionK223573 · Product code: **MNR** · Neurology
Source: <https://www.510kdatabase.net/k223573/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Nov 30, 2022
Decision date	Aug 18, 2023
Days to decision	261 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Onera B.V.
Location	Eindhoven, NL
Contact	Ruben de Francisco Martin
510(k) history	4 submissions · 4 cleared · 2022-2026

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