

K210593 Onera Sleep Test System (Onera STS)Apr 6, 2022
401 days to decisionK210593 · Product code: **MNR** · Neurology
Source: <https://www.510kdatabase.net/k210593/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Mar 1, 2021
Decision date	Apr 6, 2022
Days to decision	401 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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