

**K220095 ANNE Sleep**Jul 11, 2022  
180 days to decisionK220095 · Product code: **MNR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k220095/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ventilatory Effort Recorder (MNR)
Date received	Jan 12, 2022
Decision date	Jul 11, 2022
Days to decision	180 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Sibel, Inc.</b>
Location	Niles, IL, US
Contact	Peter Xu
510(k) history	3 submissions · 3 cleared · 2021-2022

**CLINICAL EVIDENCE - NCT04643782****Comparative Study of the ANNE™ One System to Diagnose Obstructive Sleep Apnea**

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Status	Completed
Enrollment	287 patients (actual)
Study sites	4 sites
Condition studied	Obstructive Sleep Apnea of Adult
Primary purpose	Diagnostic
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Dec 27, 2021
Sponsor	Northwestern University (Other)

**Primary outcome****Sensitivity and Specificity of Obstructive Sleep Apnea (OSA) Diagnosis Using ANNE Sleep System Compared to Polysomnography**Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT04643782](https://clinicaltrials.gov/study/NCT04643782)