

K233501 “LARGAN Health AI-Tech” Sleep Apnea and Sleep Quality Examination System (ST-SLP03A)Jul 26, 2024
269 days to decisionK233501 · Product code: MNR · Anesthesiology
Source: <https://www.510kdatabase.net/k233501/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ventilatory Effort Recorder (MNR) |
| Date received | Oct 31, 2023 |
| Decision date | Jul 26, 2024 |
| Days to decision | 269 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Largan Medical Co., Ltd. |
| Location | Taichung, TW |
| Contact | Shih-min Chen |
| 510(k) history | 8 submissions · 8 cleared · 2017-2025 |

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