

**K251480 PV01 PVDF Effort Sensor**Aug 29, 2025  
108 days to decisionK251480 · Product code: **SFK** · Anesthesiology  
Source: <https://www.510kdatabase.net/k251480/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Respiratory Effort Belt For Polysomnography (SFK) |
| Date received         | May 13, 2025                                      |
| Decision date         | Aug 29, 2025                                      |
| Days to decision      | 108 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Neurotronics, LLC</b>  |
| Location       | Alachua, FL, US   |
| Contact        | James Smith   |
| Website        | <a href="https://neurotronics.com">https://neurotronics.com</a> |
| 510(k) history | 1 submissions · 1 cleared · 2025-2025                           |

Neurotronics, LLC is a medical device company specializing in sleep diagnostics and anesthesiology devices, with a manufacturing facility in Alachua, US. The company develops advanced diagnostic software, sensors, and monitoring equipment for sleep medicine and clinical applications. Neurotronics has received FDA 510(k) clearance from total submission. The company's regulatory focus is entirely within anesthesiology devices. The first and latest clearance occurred in 2025, reflecting active regulatory engagement. The company's product portfolio includes Polysmith sleep di...

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Device record: <https://www.510kdatabase.net/k251480/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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