

**K251165 Saans (F4-01-00-000-000)**Jan 6, 2026  
266 days to decisionK251165 · Product code: **SGR** · Anesthesiology  
Source: <https://www.510kdatabase.net/k251165/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                              |
| Submission type       | Traditional   |
| Device classification | Noninvasive Positive Airway Pressure System, Facility Use (SGR) |
| Date received         | Apr 15, 2025  |
| Decision date         | Jan 6, 2026   |
| Days to decision      | 266 days  |
| Third-party review    | No  |
| Combination product   | No  |
| PCCP authorized       | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

|                |  |
|----------------|--|
| Company        | <b>Innaccel Technologies Private Limited</b> |
| Location       | Bengaluru, IN                                |
| Contact        | Vijayarajan Alagumalai                       |
| 510(k) history | 1 submissions · 1 cleared · 2026-2026        |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251165/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026