January 6, 2026

Innaccel Technologies Private Limited
Vijayarajan Alagumalai
Director and Head QARA
Aanand Towers, Municipal No 4,
Rajaram Mohan Roy Road, Ward 77, Sampangiramanagar
Bengaluru, Karnataka 560025
India

Re: K251165
Trade/Device Name: Saans (F4-01-00-000-000)
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: SGR
Dated: December 11, 2025
Received: December 11, 2025

Dear Vijayarajan Alagumalai:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
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Office of Product Evaluation and Quality
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251165

Device Name

Saans

Indications for Use *(Describe)*

The Saans System is intended to provide continuous positive airway pressure (CPAP) support to spontaneously breathing neonates and infants weighing up to 10 kg who require respiratory assistance, including those with conditions associated with prematurity such as Respiratory Distress Syndrome (RDS). The device is intended for use in hospital environments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510k Summary for Saans

1 Submitter

InnAccel Technologies Private Limited
Aanand Towers, Municipal No 4,
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Bengaluru, Karnataka, India 560025

Contact Person: Nitesh Jangir
Phone: +91 99015 33090
Date Prepared: November 25, 2025

2 Device Name

Name of Device:	Saans
Common or Usual Name:	CPAP System
Classification Name:	Continuous Ventilator (21 CFR 868.5895)
Regulatory Class:	Class II

3 Predicate Devices and Reference Devices

3.1 Predicate Device

Predicate Device Trade Name: Nihon Kohden NKV-440 Ventilator System

510(K) Number: K222644

3.2 Reference Device 1

Reference Device Trade Name: Fisher and Paykel Healthcare Bubble CPAP System

510(K) Number: K100011

4 Device Description

The Saans System is a medical device designed to deliver Continuous Positive Airway Pressure (CPAP) therapy. The Saans System consists of the Saans device and accessories that work together to deliver the required therapy to the patient. This submission covers the Saans Device. The Saans device takes ambient air and oxygen as input and provides the mixed gas as output. This gas mixture is supplied to the humidifier, the output of which is connected to the breathing circuit. The breathing circuit is connected to the patient interface and the Bubble CPAP Generator.

The key features and functionalities of the Saans System are:

Gas Source and Mixture: The system utilizes an oxygen source and ambient air to create the required gas mixture for therapy. This blending approach allows for oxygen delivery to the patient.

User Interface and Control: The system incorporates a user interface enabling users to adjust and monitor various therapy parameters. Users can set the desired flow rate and oxygen concentration (FiO2).

Pressure Regulation: A Bubble CPAP Generator is employed to achieve the desired pressure levels within the system. The generator provides a continuous positive pressure in the patient's airways.

Monitoring: The Saans System provides displays of parameters such as delivered flow, pressure, and FiO2. The pressure is measured at the end of the inspiratory limb, right before the patient interface.

Safety: The Saans System provides safety alarms like blockage, leakage and FiO2 alarms

Delivery Mechanism: Heated and humidified respiratory gas is delivered to the patient through an inspiratory breathing circuit (Inspiratory Limb) connected to a nasal interface (Patient Interface). An expiratory circuit (Expiratory Limb) completes the loop, connecting the nasal interface to the Bubble CPAP Generator for pressure regulation.

Humidification and Accessories: An external humidifier is used to provide humidified gas. The details for the breathing circuits, nasal interface, humidification chamber, and Bubble CPAP generator are all a part of the information provided to the user in the User Manual..

5 Intended Use

The Saans System is a continuous ventilator intended to assist patient breathing by delivering continuous positive airway pressure (CPAP) with a controlled mixture of air and oxygen. The device is intended for non-invasive respiratory support in hospital environments.

6 Indications for Use

The Saans System is intended to provide continuous positive airway pressure (CPAP) support to spontaneously breathing neonates and infants weighing up to 10 kg who require respiratory assistance, including those with conditions associated with prematurity such as Respiratory Distress Syndrome (RDS). The device is intended for use in hospital environments.

7 Contraindications

- Absence of spontaneous breathing
- Upper airway anomalies that impair CPAP delivery
- Congenital diaphragmatic hernia before surgical repair
- Untreated or suspected air leaks (e.g., pneumothorax)
- Severe birth asphyxia
- Severe cardiovascular or hemodynamic instability
- Recent facial or nasal trauma, surgery, or skin breakdown at the CPAP interface site
- Lack of trained clinical personnel to administer and monitor CPAP therapy
- Any condition where CPAP is deemed clinically inappropriate or harmful by a qualified clinician

8 Predicate comparison

The Saans System has been evaluated against the predicate device, the Nihon Kohden NKV-440 Ventilator System (K222644), and is considered substantially equivalent.

The table below captures the comparison in detail:

Sl No.	Feature/Characteristic for comparison	Subject device SAANS system	Predicate Device Nihon Kohden NKV-440 Ventilator system (K222644)	Comparison
1	K#	K251165	K222644	
2	Legal Manufacturer	Innaccel Technologies Pvt Ltd	Nihon Kohden OrangeMed, Inc.	

3	Indications For Use	The Saans System is intended to provide continuous positive airway pressure (CPAP) support to spontaneously breathing neonates and infants weighing up to 10 kg who require respiratory assistance, including those with conditions associated with prematurity such as Respiratory Distress Syndrome (RDS). The device is intended for use in hospital environments.	The Nihon Kohden NKV-440 Ventilator System is intended to provide continuous ventilation for adult, pediatric and neonatal patients who require invasive or noninvasive respiratory support. The NKV-440 offers mandatory and spontaneous ventilation modes as well as respiratory monitoring. The NKV-440 is intended for use in hospitals and hospital-type facilities, as well as, for in-hospital transportation.	The Saans System is intended for a narrower patient population covering spontaneously breathing neonates and infants weighing up to 10 kgs.
4	Life supporting or Life sustaining	Yes	Yes	Similar
5	Environment of use	Hospital	Use in hospitals and hospital-type facilities, which provide respiratory care for patients requiring respiratory support. The device may be used for intra-hospital transport	The Saans System is intended to be used only in the Hospital environment.

6	Design and operating principle	Consists of an LED display user interface to set the Flow, FiO2, and to monitor the Pressure, delivered flow and FiO2; Controls air and oxygen deliveries by a blower and proportional valve through a microprocessor. Controls the pressure through a bubble CPAP generator	Consists of a graphic user interface to set and monitor ventilation, breath delivery unit, breathing circuit, and cart; Controls air and oxygen deliveries by a blower and proportional valve through microprocessors	The Saans system makes use of a blower and a proportional valve to control the air and oxygen delivered, similar to the predicate device. Meanwhile pressure regulation occurs externally through a bubble CPAP generator placed in the expiratory limb, similar to the reference device.
7	Oxygen input range	10-70 PSI (70-483kPa)	Low pressure: 11 PSI (75 kPa) High pressure: 41 to 87 PSI (283 to 600 kPa)	Similar
8	Flow Range	2-15 L/min	1 to 15 L/min Neonate	Similar
9	Pressure range	2-10 cmH2O	0 to 30 cmH2O Neonate	The Saans System operates in a narrower CPAP pressure range.
10	FiO2 range	21%-100%	21% - 100%	Similar
11	Stand-alone battery Life	4-6 Hours	Backup battery: 1 h 30 min Extended battery: 3 h 30 min	Similar

12	Breathing modes	Non-Invasive Ventilation: CPAP	Invasive Ventilation: A/CMV-PC A/CMV-VC A/CMV-PRVC SIMV-PC-PS SIMV-VC-PS SIMV-PRVC-PS SPONT-CPAP SPONT-PS SPONT-VS APRV Non-Invasive Ventilation: A/CMV-PC SIMV-PC-PS SPONT-CPAP SPONT-PS APRV CPAP O2 Therapy	The Saans System only offers the CPAP mode of respiratory support.
13	Alarms method	Visual and audible alarms	Visual and audible alarms	Similar
14	Operating condition Temperature, Pressure, Humidity	Temperature- 5-50°C Relative Humidity-15- 85% non-condensing Atmospheric Pressure- 510 to 1122 cmH2O (500 to 1100 hPa)	Temperature: 10 to 40°C (50 to 104°F) Humidity: 10 to 95% non–condensing Atmospheric pressure: 700 to 1060 hPa	Similar

9 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing
As part of a biocompatibility assessment per ISO 10993-1, it was determined that only the ISO 18562 series is applicable for this device, given the nature of patient contact.
The biocompatibility evaluation was conducted in accordance with the ISO 18562-1 Second edition 2024-03, ISO 18562-2 Second edition 2024-03, and ISO 18562-3 Second edition 2024-03 as recognized by the FDA.

Electrical Safety, Electromagnetic Compatibility (EMC), Software, and Alarms
Electrical safety and EMC testing were conducted on the Saans system in accordance with IEC 60601-1 Edition 3.2 2020-08, IEC 60601-1-2 Edition 4.1 2020-09.

Alarms testing was performed in accordance with IEC 60601-1-8 Edition 2.2 2020-07. The testing demonstrated the appropriate electrical safety and electromagnetic compatibility profile for the device.

Software Verification and Validation Testing
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."

Cleaning/Reprocessing
The cleaning/reprocessing validation has been done in accordance with AAMI ST98: Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices.

Bench / Performance Testing
Performance testing, including blending accuracy, flow rate accuracy, and pressure accuracy, was performed to demonstrate substantial equivalence.

Human Factors & Usability Engineering
Evaluated in compliance with IEC 62366-1 Edition 1.1 2020-06 through formative and summative usability testing.

The nonclinical verification and validation testing - including performance, biocompatibility, electrical safety, electromagnetic compatibility, usability, and software testing - demonstrate that the Saans System meets all design specifications and performance requirements. No new clinical data were necessary. Based on this testing and the Clinical Evaluation Report referencing comparable devices, the Saans System is as safe and as effective as, and performs as well as, the predicate device.

Standard complied to

- ISO 5356-1:2015 Anaesthetics and respiratory equipment- Conical connectors: Part 1: Cones and sockets
- ISO 18082:2014 Anaesthetic and respiratory equipment-Dimension of non-interchangeable screw-thread (NIST) low-pressure connectors for medical gases
- ISO 18562-1:2024 Biocompatibility evaluation of breathing gas pathway in healthcare Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2024 Biocompatibility evaluation of breathing gas pathway in healthcare Part 2 : Test for emissions of particulate matter
- ISO 18562-3:2024 Biocompatibility evaluation of breathing gas pathway in healthcare Part 3: Tests for emissions of volatile organic substances
- ISO 14971:2019 Medical devices- Application of risk management to medical devices
- ISO 62366-1:2015+AMD1:2020 Part 1: Application of usability engineering to medical devices
- IEC 60601-1 Edition 3.2 2020-08 Medical electrical equipment- Part 1: General requirements for basic and essential performance

- IEC 60601-1-2:2014 [Including AMD 2:2021] Medical electrical equipment- Part 1-2: General requirements for basic safety and essential performance- Collateral standard: Electromagnetic disturbance-Requirements and tests
- IEC 60601-1-8:2006 and A1:2012 [Including AMD2:2021] Medical electrical equipment- Part 1-8:General requirements for basic safety and essential performance-Collateral standard:General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- ISO 15223-1Fourth edition 2021-07 Medical devices -Symbols to be used with information to be supplied by the manufacturer Part 1: General requirements
- IEC 63204:2006/A1:2016 Medical device software- software life cycle process
- ISTA 3A 2018 Packaged-products for parcel delivery system shipment 70 Kg(150 Lb) or less
- IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems
- ISO 20417:2021 Medical devices - Information to be supplied by the manufacturer
- IEC 60601-4-2:2024 Medical electrical equipment- Part 4-2: Guidance and interpretation- Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- ANSI ST98:2022 Cleaning validation of health care products- Requirements for development and validation of a cleaning process for medical devices
- ISO 10993-1:2018 Biological evaluation of medical devices Part 1:Requirements and general principles for the evaluation of biological safety within a risk management process
- ISO 5359:2014 Anaesthetic and respiratory equipment -Low-pressure hose assemblies for use with medical
- ISO 4135:2022 Anaesthetic and respiratory equipment-Vocabulary

Guidance referred to:

- Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices
- The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]
- Medical Device Accessories Describing Accessories and Classification Pathways
- Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff
- Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions
- Electromagnetic Compatibility (EMC) of Medical Devices
- Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions
- Acceptance of Clinical Data to Support Medical Device Applications and Submissions Frequently Asked Questions
- Applying Human Factors and Usability Engineering to Medical Devices

10 Substantial Equivalence Conclusion

InnAccel Technologies Pvt. Ltd. has demonstrated through design, features, and non-clinical testing that the subject device (Saans System) is substantially equivalent to the predicate device in CPAP mode (Nihon Kohden NKV-440 Ventilator System, K222644)