December 23, 2024

Inogen, Inc.
% Michael Nilo
President and Principal Consultant
Nilo Medical Consulting Group
3706 Butler Street
#313
Pittsburgh, Pennsylvania 15201

Re: K241091
Trade/Device Name: SIMEOX 200 Airway Clearance Device
Regulation Number: 21 CFR 868.5665
Regulation Name: Powered Percussor
Regulatory Class: Class II
Product Code: SDT
Dated: November 27, 2024
Received: November 27, 2024

Dear Michael Nilo:

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, Respiratory Devices Team
DHT1C: Division of Sleep Disordered
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241091

Device Name
SIMEOX 200 Airway Clearance Device

Indications for Use *(Describe)*
The SIMEOX 200 airway clearance device is intended to promote airway clearance and to improve bronchial drainage by enhancing mobilization of bronchial secretions via high frequency oscillatory vibrations and intermittent negative pressure to the airway during exhalation. The device is intended to be prescribed for use in patients capable of independently generating cough.
SIMEOX 200 is intended for use in the home, hospital, and other healthcare institutions by individuals weighing at least 23 Kg.

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.

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510(K) SUMMARY

DATE OF PREPARATION	December 20, 2024
APPLICANT	Inogen, Inc. 859 Ward Drive Suite 200 Goleta, California 93111
OFFICIAL CORRESPONDENT	Michael Nilo, MS BME, President Nilo Medical Consulting Group 3706 Butler Street, #313 Pittsburgh, PA 15201 Phone: (717) 421-4396 E-mail: michael.nilo@nilomed.com
DEVICE NAME	SIMEOX 200 Airway Clearance Device
DEVICE CLASSIFICATION	Common Name: Powered percussor Regulation: 21 CFR 868.5665 Class II
PRIMARY PREDICATE DEVICE	AirPhysio Positive Expiratory Pressure (PEP) Device (K203209)
SECONDARY PREDICATE DEVICE	Philips Respironics SimplyClear Device (K122111)

DEVICE DESCRIPTION

The SIMEOX 200 Airway Clearance Device consists of a portable generator and a single patient use expiratory kit. The patient inhales from the ambient environment, naturally and independent of the device, and then exhales into the device mouthpiece. During the patient's exhalation, the SIMEOX 200 generates a pneumatic vibration throughout the airway. This vibration, applied at 6 Hz or 12 Hz via negative pressure pulses, disseminates throughout the bronchial tree in order to decrease mucus viscosity and increase secretion mobility. During or after therapy, the patient can clear the secretions by coughing independently.

The SIMEOX 200 device is housed within an acrylonitrile butadiene styrene polycarbonate (ABS/PC) unit, with control buttons located on the front and top panels. The "Go" button, which is located on the front panel of the device, is used to start the pneumatic vibration signal of SIMEOX 200. Beneath the "Go" button is a connection inlet for the expiratory kit and mouthpiece. This inlet is equipped with a stainless-steel grid to prevent large particles from penetrating inside the air circuit. The remote controller has a redundant "Go" button for ease of use. The device also has an external power supply with an AC cord, and an optional Lithium-Ion battery.

Expiratory kits, which consist of the mouthpiece and respiratory tubing, are available in two different versions and are supplied separately from the SIMEOX 200 device. TUB10 expiratory kits come with one polyvinyl chloride (PVC) respiratory tube, one styrene-butadiene copolymer (SBC) filter with a polypropylene membrane, and 10 single-use polypropylene mouthpieces, each intended to be disposed of after each use. Similarly, TUB25 expiratory kits come with one PVC respiratory tube, one SBC filter with a polypropylene membrane, and 3 reusable polypropylene mouthpieces, each intended to be used up to ten times. The filters supplied in both kits each come with an RFID tag, which tracks the number of uses of the filter and tube. The RFID tag ensures that the device will not operate upon connection to an expiratory kit that has expended its maximal number of uses (10 maximal uses for TUB10, and 25 maximal uses for TUB25).

INDICATIONS FOR USE

The SIMEOX 200 airway clearance device is intended to promote airway clearance and to improve bronchial drainage by enhancing mobilization of bronchial secretions via high frequency oscillatory vibrations and intermittent negative pressure to the airway during exhalation. The device is intended to be prescribed for use in patients capable of independently generating cough.

SIMEOX 200 is intended for use in the home, hospital, and other healthcare institutions by individuals weighing at least 23 Kg.

PRINCIPLES OF OPERATION / MECHANISM OF ACTION

The SIMEOX 200 Airway Clearance Device promotes airway clearance by loosening and mobilizing secretions. Therapy is delivered via exhalation into the device plastic mouthpiece. During exhalation, a high frequency negative pressure oscillation (pneumatic vibration) is applied to the airways which loosens mucus from the bronchial walls, increasing its mobilization.

Airway oscillation (vibration) during exhalation is an established mechanism of action used to loosen mucus and mobilize secretions from the airways for expectoration.

KEY TECHNICAL SPECIFICATIONS

The SIMEOX 200 has two different Therapy settings. The first is Standard Mode, which can be set to 25%, 50%, 75%, or 100% power. Standard Mode gives the same amount of air flow while you breathe out into the device for your entire exhalation. The other type of Therapy mode is ADAPT Mode. With ADAPT Mode, the device will decrease the amount of airflow during your exhalation, which may make breathing into the device more comfortable.

The SIMEOX 200 has two different Trigger settings, also. The first is a Manual Trigger, which means the device will not start the airflow unless you press the GO button, either the button on the device on the one on the remote control. The other Trigger is the DETECT Trigger. When the DETECT Trigger is chosen, the GO button must be pressed, but the device will not start air flow therapy until you begin breathing out into the mouthpiece. This may help you if it is difficult to coordinate the GO button with your exhalations.

Both Therapy Modes can be used with both Trigger Modes, so any combination of Therapy and Trigger may be chosen.

A summary of key specifications for device operation are as follows:

- Power Modes: Standard Mode (adjustable at 25%, 50%, 75%, or 100% total power)* and Adapt Mode (power is automatically regulated by the device, consisting of decreased power over the course of each exhalation).
- Cycle Duration: 10 breaths (exhalations). The device generates vibration during exhalation into the device mouthpiece.
- Oscillation Frequency: 12 Hz for the first eight (8) exhalations of each 10-breath cycle and 6 Hz for the last two (2) exhalations of each 10-breath cycle, to enable secretion transport.
- Duration of treatment: The device will perform a maximum of 10 cycles (i.e., 100 exhalations) or 60 minutes of therapy, whichever occurs first, prior to shutting down, for each mode of operation.
- Activation of Therapy (Detect and Manual Trigger): In Detect Trigger, after the patient presses the 'Go' button, the device does not deliver a signal until it detects patient exhalation has begun. With the device set to Manual Trigger, therapy is initiated as soon as the 'Go' button is activated.

SUBSTANTIAL EQUIVALENCE

The SIMEOX 200 Airway Clearance Device is substantially equivalent in intended use and technological characteristics to two predicate devices. The primary predicate device for the SIMEOX 200 is the AirPhysio device (K203209). The secondary predicate is the SimplyClear device (K122111). All three devices, the subject device and the two predicates, are intended to improve the clearance of mucosal secretions from the airways by vibrating the airway walls to assist in loosening mucus. All three devices apply this vibration during exhalation into the device via a patient mouthpiece. All three devices may be used with therapy being delivered during

exhalation-only, with inhalation occurring at an ambient/atmospheric pressure: this is inherent to the SIMEOX 200 and AirPhysio devices, and this is one available operating mode for the SimplyClear Device, namely, exsufflation-only mode.

The following table summarizes the key technical characteristics between the SIMEOX 200 Airway Clearance Device, the SimplyClear Device, and the AirPhysio Device.

	SUBJECT DEVICE (SIMEOX-200)	PRIMARY PREDICATE (AIRPHYSIO)	SECONDARY PREDICATE (SIMPLYCLEAR)	SUMMARY/ DISCUSSION
Product Name	**SIMEOX-200 Airway Clearance Device**	**AirPhysio Positive Expiratory Pressure (PEP) Device**	**SimplyClear Device**	N/A
Manufacturer	Inogen, Inc.	AirPhysio Pty Ltd	Philips Respironics Inc., USA	N/A
510(k) number	K241091	K203209	K122111	N/A
Regulatory Classification	21 CFR 868.5665	21 CFR 868.5665	21 CFR 868.5665	Identical
Regulatory Identification	A powered percussor is a device that is intended to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage and that may be powered by electricity or compressed gas.	A powered percussor is a device that is intended to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage and that may be powered by electricity or compressed gas.	A powered percussor is a device that is intended to transmit vibration through a patient's chest wall to aid in freeing mucus deposits in the lung in order to improve bronchial drainage and that may be powered by electricity or compressed gas.	Identical
Classification	Class II	Class II	Class II	Identical
Indications for Use	The SIMEOX 200 airway clearance device is intended to	AirPhysio is indicated for use as a Positive Expiratory	Intended Use: The Philips Respironics SimplyClear device	Identical: All 3 devices are intended to assist

	promote airway clearance and to improve bronchial drainage by enhancing mobilization of bronchial secretions via high frequency oscillatory vibrations and intermittent negative pressure to the airway during exhalation. The device is intended to be prescribed for use in patients capable of independently generating cough. SIMEOX 200 is intended for use in the home, hospital, and other healthcare institutions by individuals weighing at least 23 Kg.	Pressure (PEP) Device for improving the clearance of mucus secretions from the airways. AirPhysio vibrates the airway walls to assist in loosening mucus and intermittently increases endobronchial pressure so that the airway patency can be maintained during exhalation, reducing the potential of mucus becoming trapped as it moves up the airways. The device may also be useful in the removal of mucus from patients who have chronic bronchitis or bronchiectasis and in conjunction with a medical need for positive expiratory pressure (PEP) therapy.	assists patients in loosening, mobilizing and clearing secretions by providing high frequency oscillatory vibrations while gradually applying a positive pressure to the airway, then rapidly shifting to a negative pressure. The oscillatory vibrations assist in loosening and mobilizing the secretions while the rapid shift in pressure produces a high expiratory flow rate from the lungs, which promotes the clearance of secretions. Indications for Use: The SimplyClear device may be used either with a facemask or mouthpiece, or with an adapter to a patient's endotracheal or tracheostomy tube. It is for use on adult or pediatric patients having difficulty with secretion clearance and/or inability to cough.	patients in loosening, mobilizing and clearing secretions by providing high frequency oscillatory vibrations to the airways. Different: Only SimplyClear is intended for patients with "inability to cough", therefore SIMEOX-200 treats a subset of SimplyClear intended use. Only SimplyClear is intended for patients with endotracheal or tracheostomy tube, therefore SIMEOX 200 treats a subset of the SimplyClear intended use. SIMEOX 200 and the SimplyClear in exsufflation-only mode deliver vibration negative pressure during exhalation. AirPhysio delivers vibration

			The SimplyClear device is for use in a hospital, institutional environment or in the home.	via positive pressure during exhalation.
Device Description	The SIMEOX 200 Airway Clearance Device consists of a portable generator and single patient use expiratory kit. The device promotes airway clearance by loosening and mobilizing secretions. Therapy is delivered via exhalation into the device plastic mouthpiece. During exhalation, a high frequency negative pressure oscillatory vibration is applied to the chest wall via the airways and loosens mucus from the bronchial walls, increasing mobilization.	AirPhysio is a small, handheld expiration resistance device, consisting of a hardened plastic mouthpiece at one end, a plastic cover with an opening at the other end, and a valve on the inside created by a high-density stainless-steel ball resting in a plastic conical cone. Exhalation through the device causes vibrations, assisting to loosen mucus from the airways. The resistance is increased by tilting the device.	The Philips Respironics SimplyClear device promotes airway clearance by loosening, mobilizing and clearing secretions. The loosening and mobilization occur by gradually applying air pulse generated high frequency oscillatory vibrations on the positive and negative pressures applied to the chest wall via the airways. The high frequency oscillatory vibrations release mucus from the bronchial walls, increasing mobilization. The positive to negative shift in pressure produces a high expiratory flow from the lungs, promoting the clearance of the mobilized secretions via coughing.	Identical: All devices deliver the mechanism of action of loosening mucus in the airways via application of vibration to the airways during exhalation. The SimplyClear may be operated in an exsufflation-only mode, in which no positive pressure is administered during inhalation. The SIMEOX 200 does not include the SimplyClear feature of rapid pressure changes to generate cough, and therefore, the SIMEOX 200 is intended for a subset of the Simply Clear indications: namely, the loosening of

				mucus, but not the generation of cough. SIMEOX 200 is intended for patients who can generate a cough independently.
Principles of Operation / Mechanism of Action	Airway Oscillation (vibration) during exhalation to loosen mucus and mobilize secretions from the airways for expectoration (pneumatic oscillation)	Airway Oscillation (vibration) during exhalation to loosen mucus and mobilize secretions from the airways for expectoration combined with Positive Expiratory Pressure (PEP)	Airway Oscillation (vibration) during exhalation-only and/or during inhalation and exhalation to loosen mucus and mobilize secretions from the airways for expectoration. Insufflation-exsufflation mode available to assist patients with inability to cough.	All devices operate on the mechanism of high frequency oscillatory vibration applied within the airways in order to loosen and mobilize mucus, enabling removal via expectoration.
Patient Population	Patients having difficulty with secretion clearance. Patients weighing > 23 Kg*	Patients who have chronic bronchitis or bronchiectasis	Adult or pediatric patients having difficulty with secretion clearance and/or inability to cough	Identical: All devices are intended to treat patients having difficulty clearing secretions. SimplyClear is labeled for both adult and pediatric patients whereas SIMEOX-200 is labeled for patients weighing >23 Kg. Different: Only SimplyClear is

				intended for patients with "inability to cough", therefore SIMEOX-200 treats a subset of those who can use SimplyClear.
Environments of Use	Home / Healthcare facility	Home / Healthcare facility	Home / Healthcare facility	Identical
Prescription / OTC	Prescription	Prescription	Prescription	Identical
Patient Interface	Mouthpiece	Mouthpiece	Mouthpiece Facemask, tracheostomy or endotracheal tube.	Identical: Mouthpiece Different: Facemask, tracheostomy or endotracheal tubes are only interface options for the SimplyClear device; therefore SIMEOX-200 treats a subset of those who can use SimplyClear.
Phases of Therapy	Exsufflation Only	Exsufflation Only	Exsufflation-Only Mode Available; Insufflation/Exsufflation (I-E) Mode Available	Identical: All devices operate in exsufflation-only mode Discussion: The I-E mode available on the SimplyClear device is out of scope for predicate comparison in the context of the SIMEOX-200, which offers a

				subset of the SimplyClear capabilities.
Power Source	Battery or Mains Power	None; Manual Exhalation-Powered Device	Battery or Mains Power	Identical: SIMEOX-200 and SimplyClear are both powered by battery or mains power Discussion: AirPhysio is a mechanically powered device and therefore the SimplyClear is the technological reference for this characteristic.
Modes of Operation	Manual or Auto	Manual	Manual or Auto	Identical: SIMEOX-200 and SimplyClear are both operated with either Manual or Auto Mode Discussion: AirPhysio is a mechanically powered device and therefore the SimplyClear is the technological reference for this characteristic.
Power/ Flow Settings	Manual Mode : Available Power Settings (25%; 50%; 75% or 100%) Auto Mode : Power Setting is servo-controlled	Manual	Low, Medium, High	Identical: SIMEOX-200 and SimplyClear are both able to be operated in different power modes. SIMEOX-200 operating

				conditions are within the range available for the SimplyClear
High-frequency oscillations	Yes (during exhalation only)	Yes (during exhalation only)	Yes (available during exhalation only; and/or available during inhalation/exhalation)	Identical
Exhalation Pressure (Negative)	0 to -60 cm H_2O	N/A	0 to -70 cm H_2O	Identical: SIMEOX-200 pressure range is nearly identical to that of SimplyClear and falls within a subset of the SimplyClear available negative pressure range. Discussion: AirPhysio is a mechanically powered device and therefore the SimplyClear is the technological reference for this characteristic.
Inhalation Pressure (Positive)	Atmospheric (0 cm H_2O)	Atmospheric (0 cm H_2O)	0 to 70 cm H_2O	Identical: All devices operate in exsufflation-only mode. Discussion: Bench verification testing of the SIMEOX 200 confirms the device operates

				within its prespecified operating specifications for negative pressure delivery, which are in keeping with those of the predicate devices set to exsufflation-only (Positive pressure setting of 0 cm H_2O). This demonstrates that the SIMEOX 200 performs to the same critical input and output specifications as the predicate devices.
Oscillation Frequencies	Fixed Frequencies 12 Hz (first 8 phases of treatment cycle) 6 Hz (final two phases of treatment cycle)	Variable Frequencies (Determined by user tilting the device)	Variable Frequencies (User selected) Range: 0 to 20 Hz	Identical: Frequencies available with SIMEOX 200 therapy are within the available frequencies during SimplyClear treatment. Discussion: AirPhysio is a mechanically powered device and therefore the SimplyClear is the technological reference for this

				characteristic.¥
User Interface	Activation buttons, Hierarchal menu system, Visual feedback on device respiratory outputs	None	- Activation buttons - Hierarchal menu system - Visual feedback on device respiratory outputs	Identical: SIMEOX 200 and SimplyClear allow for the control of therapy and visual feedback via a user interface. Discussion: AirPhysio is a mechanically powered device and therefore the SimplyClear is the technological reference for this characteristic.

PERFORMANCE DATA PRESENTED IN THIS 510(K)

Performance verification testing was conducted on the bench with the SIMEOX 200 Airway Clearance Device to demonstrate the subject device performs to its pre-specified requirement specifications, which align with those of the predicate devices. . The SIMEOX 200 device also went through comprehensive software verification and validation testing to confirm the device operates within specification. Testing demonstrated the SIMEOX 200 performed as intended and was safe and effective.

Biocompatibility testing was conducted in accordance with ISO 10993-1, and these studies concluded the SIMEOX 200 expiratory kit accessories were not considered cytotoxic, sensitizing or irritating and were demonstrated and biocompatible for their intended use.

A human factors validation study was conducted with simulated first-time use of the product in adult users and dyads of children with caregivers. The study concluded that the device is safe for its intended users.

Comprehensive cybersecurity, wireless, electromagnetic compatibility, and electrical, mechanical and thermal safety testing have been conducted.

CONCLUSIONS

The SIMEOX 200 Airway Clearance Device is substantially equivalent to the predicate devices. The SIMEOX 200 Airway Clearance Device that is the subject of this 510(k) has been validated in nonclinical testing which confirms the device complies with its specifications and operates equivalently to the cited predicates. The indications for use, technological characteristics, and principles of operation are similar to the predicate devices.

The conclusions drawn from the nonclinical testing in this submission demonstrate that the SIMOEX 200 is as safe, as effective, and performs as well as the legally marketed device predicates and therefore, that the SIMEOX 200 Airway Clearance Device is substantially equivalent to the predicate devices across its intended range of performance measures.