August 14, 2024

Dimar S.p.A
% Maurizio Pantaleoni
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Re: K232836
Trade/Device Name: Family of DIMAR DMAX NIV masks
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous ventilator
Regulatory Class: Class II
Product Code: CBK, BZD
Dated: July 9, 2024
Received: July 15, 2024

Dear Maurizio Pantaleoni:

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.

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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Center for Devices and Radiological Health

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)*
K232836

Device Name
FAMILY OF DIMAR DIMAX NIV MASKS

Indications for Use *(Describe)*
FAMILY OF DIMAR DIMAX NIV MASKS is intended to provide a patient interface for application of noninvasive ventilation.
The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilator failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency.
For single patient use in the Hospital environment
The mask is to be used on patients who are appropriate candidates for noninvasive ventilation.
The small size is intended to be used for children (from 7 years and > 20kg) while the sizes medium/large/ extra-large/ extra-extra-large are intended to be used for adolescents or adults >30 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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1. General Information

This 510(k) Summary is being submitted as required by 21 CFR 807.92

Submitter :

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Summary Preparation Date: August 13, 2024

2. Name & Classification

Device Name:	FAMILY OF DIMAR DIMAX NIV MASKS
Regulation Name:	Continuous Ventilator
Regulation Number:	868.5895
Product Code:	CBK
Secondary Product code	BZD
CLASS:	II

3. Predicate Devices

The FAMILY OF DIMAR DIMAX MASKS is substantially equivalent to the following devices legally marketed in the U.S. market:

Applicant	Device Name	510(k) Number
Respironics Inc.	Performax SE Total Face Mask (primary predicate device)	K072588
Respironics Inc.	Respironics Total Face Mask (secondary predicate device)	K992969

4. Indications for Use

FAMILY OF DIMAR DIMAX NIV MASKS is intended to provide a patient interface for application of noninvasive ventilation.
The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilator failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency.
For single patient use in the Hospital environment.

The mask is to be used on patients who are appropriate candidates for non-invasive ventilation.
The small size is intended to be used for children (from 7 years and > 20kg) while the sizes medium/large/ extra-large/extra-extra-large are intended to be used for adolescents or adults >30 kg.

5. Device Description

FAMILY OF DIMAR DIMAX NIV MASKS consists of two main types of a patient interface:

- DIMAX ZERO
- DIMAX

The DIMAX ZERO MASK is a "total face" MASK that totally covers eyes, nose and mouth.
The DIMAX ZERO MASK is provided for SINGLE USE.

Below a short summary of the technical features of the DIMAX ZERO MASK:

- The MASK can be connected to 2 different connectors: 1 for gas inlet and the other one for the exhaust gas outlet (the mask can also work with 1 connector, with the hole for the second connector – gas outlet- capped);
- The MASK is fixed to the head of the patient through a 5 fixing points headgear;
- A silicon gasket allows the mask to adapt to the patient's face and avoid air leaks;
- 2 specific luer ports are available for the control of the pressure through a manometer;
- The DIMAX ZERO MASK is provided not sterile in a plastic pouch. In each pouch are included the following connectors (22 mm connectors conforming to ISO 5356-1) and components:
    - 22F Non-Vented connector;
    - 22F Vented connector with flop;
    - 22F Non-Vented connector with FBS port;
    - 22M-22M adapter;
    - 22F-22F adapter;
    - 22F cap.

The DIMAX MASK is a "Total Face" MASK that totally covers eyes, nose and mouth.
The DIMAX MASK is provided for SINGLE USE.

Below a short summary of the technical features of the DIMAX MASK:

- The MASK can be connected through the same connector for both gas inlet and exhaust gas outlet;
- The MASK is fixed to the head of the patient through a 5 fixing points headgear;
- A silicon gasket allows the mask to adapt to the patient's face and avoid air leaks;
- 2 specific luer ports are available for the control of the pressure through a manometer;
- The DIMAX MASK is provided not sterile in a plastic pouch. In each pouch are included the following connectors (22 mm connectors conforming to ISO 5356-1) and components:
    - 22F Non-Vented connector;
    - 22F Vented connector with flop;
    - 22F Non-Vented connector with FBS port.

6. Comparison with the predicate devices

PRODUCT NAME	SUBJECT DEVICE: FAMILY OF DIMAR DIMAX NIV MASKS		PREDICATE DEVICE (primary)	PREDICATE DEVICE (secondary)	
	DIMAX MASK	**DIMAX ZERO MASK**	**Performax SE Total Face Mask (K072588)**	**Respironics Total Face Mask (K992969)**	**Equivalence Discussion**
APPLICANT	DIMAR S.P.A.		Respironics	Respironics	/
K NUMBER	/		K072588	K992969	/
CLASSIFICATION					
DEV. CLASS	II		II	II	Identical Classification
PANEL	ANESTHESIOLOGY DEVICES		ANESTHESIOLOGY DEVICES	ANESTHESIOLOGY DEVICES	Identical Panel
REGULATION NUMBER	868.5895 – Continuous Ventilator		868.5895 – Continuous Ventilator	868.5905 Noncontinuous ventilator (IPPB)	Identical Regulation Number to primary predicate
PRODUCT CODE	CBK BZD		CBK	BZD	Identical CBK product code to primary predicate Identical BZD product code to secondary predicate
INTENDED USE					
INDICATIONS FOR USE:	FAMILY OF DIMAR DIMAX NIV MASKS is intended to provide a patient interface for application of non-invasive ventilation. The mask is to be used as an accessory to ventilators which have adequate alarms and safety systems for ventilator failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency. For single patient use in the Hospital environment The mask is to be used on patients who are appropriate candidates for non-invasive ventilation. The small size is intended to be used for children (from 7 years and > 20kg) while the sizes medium/large/ extra-large/extra-extra-large are intended to be used for adolescents or adults >30 kg		The Performax SE Total Face Mask is intended to provide a **patient interface** for application of non invasive ventilation. The mask is to be used as an **accessory to ventilators which have adequate alarms and safety systems for ventilator failure, and which are intended to administer CPAP or positive pressure ventilation for treatment of respiratory failure, respiratory insufficiency** or obstructive sleep apnea. The mask is for multi-patient reuse on patients weighing > 30 kg, who are appropriate candidates for non invasive ventilation, in the hospital/institutional environment only.	The Respironics Total Face Mask is intended to provide an **interface for application** of Respironics **CPAP** or BiPAP therapy to patients For **single patient** use in the home or Hospital/institutional environment. The mask is to be used on adult patients (> 30kg) for whom CPAP or BiPAP therapy has been prescribed using a Respironics CPAP or BiPAP system	Equivalent intended use to the predicate devices

PRODUCT NAME	SUBJECT DEVICE: FAMILY OF DIMAR DIMAX NIV MASKS		PREDICATE DEVICE (primary)	PREDICATE DEVICE (secondary)	
	DIMAX MASK	**DIMAX ZERO MASK**	**Performax SE Total Face Mask (K072588)**	**Respironics Total Face Mask (K992969)**	**Equivalence Discussion**
ENVIRONMENT	Hospital environment only.		Hospital/institutional environment only	Home or Hospital/institutional environment	Equivalent environment to predicate devices
REUSE	Single Use		Multi Patient	Single Patient	Equivalent to secondary predicate device
THERAPY FEATURES					
Principles of Operation	Devices intended to provide an interface to ventilators which are intended to administer CPAP or positive pressure ventilation directed to the patient's nostril and mouth and that are held in place with adjustable headgear that straps the mask to the face		Devices intended to provide an interface to ventilators which are intended to administer CPAP or positive pressure ventilation directed to the patient's nostril and mouth and that are held in place with adjustable headgear that straps the mask to the face	Devices intended to provide an interface for application of Respironics CPAP or BiPAP therapy to patients directed to the patient's nostril and mouth and that are held in place with adjustable headgear that straps the mask to the face	Equivalent principle of operation to predicate devices
Type of Patient	From 7 years > 20kg (small size) Adult >30 kg (medium/large/ extra-large / extra-extra-large sizes)		From 7 years > 20kg (small size) Adult >30 Kg (large / extra-large sizes)	From 7 years > 20kg (small size) Adult >30 Kg (large / extra-large sizes)	Equivalent type of patient to predicate devices
Patient Support System	Positive Pressure Ventilation		Positive Pressure Ventilation	Positive Pressure Ventilation	Equivalent patient support system to predicate devices
TECHNICAL FEATURES					
Available Sizes	S M L XL XXL		S L XL	S L XL	Equivalent sizes to predicate devices
Dead Space Volume	S: 396 ml M: 698 ml L: 710 ml XL: 769 ml XXL: 1053 ml		Small = 375 ml Large = 550 ml Extra Large = 717 ml	Small = 375 ml Large = 550 ml Extra Large = 717 ml	Equivalent dead space volumes to predicate devices.
Interface to avoid leaking	Silicon seal		Silicon seal	Silicon seal	Equivalent to predicate devices

PRODUCT NAME	SUBJECT DEVICE: FAMILY OF DIMAR DIMAX NIV MASKS		PREDICATE DEVICE (primary)	PREDICATE DEVICE (secondary)	
	DIMAX MASK	**DIMAX ZERO MASK**	**Performax SE Total Face Mask (K072588)**	**Respironics Total Face Mask (K992969)**	**Equivalence Discussion**
Tubing connection points	Connection points compliant to ISO 5356-1		Connection points compliant to ISO 5356-1	Connection points compliant to ISO 5356-1	Equivalent to predicate devices
Minimum Therapy Pressure	4 cm H_2O		4 cm H_2O	4 cm H_2O	Equivalent to predicate devices
PERFORMANCES					
Resistance Flow	**S and XXL** 50 SLPM: 0.2 cm H_2O 100 SLPM:0.5 cm H_2O		Unknown	Resistance Flow for EE elbow 50 SLPM: 0.52 cm H_2O 100 SLPM:1.07 cm H_2O	Equivalent resistance to flow to secondary predicate device
Rebreathing (test 1) **Comparative tests NC**	**S** 4 cm H_2O = 34% 5 cm H_2O = 31% 10 cm H_2O = 21,5% **XL** 4 cm H_2O = 35.8% 5 cm H_2O = 33.1% 10 cm H_2O = 25.1% **XXL** 4 cm H_2O = 39% 5 cm H_2O = 35.5% 10 cm H_2O = 32.8%	**S** 4 cm H_2O = 23,3% 5 cm H_2O = 19,6% 10 cm H_2O = 18,6% **XL** 4 cm H_2O = 23.8% 5 cm H_2O = 20.5% 10 cm H_2O = 13.4% **XXL** 4 cm H_2O = 24.5% 5 cm H_2O = 20.3% 10 cm H_2O = 16.2%	Unknown	**S** 4 cm H_2O = 55,1% 5 cm H_2O = 50,4% 10 cm H_2O = 43,4% **XL** 4 cm H_2O = 40.3% 5 cm H_2O = 35.8% 10 cm H_2O= 34.3%	Equivalent rebreathing to secondary predicate device
Rebreathing (test 2) Comparative tests SFC	S = 89,7% XL = 91.1% XXL = 101.6%	S = 83.7% XL = 82.3% XXL = 90.7%	Unknown	S = 98,2% XL = 103.5%	Equivalent rebreathing to secondary predicate device
Rebreathing (test 3) Comparative tests SFC	S = 99% XL = 101.1% XXL = 102.8%	S = 93.3% XL = 103.3% XXL = 104.2%	Unknown	S = 95,8% XL = 104.6%	Equivalent rebreathing to secondary predicate device

7. Performance Data

A program of design verification and validation testing was performed that includes the following:

- Connections and ports (This device has been tested to ISO 17510:2015 Medical devices – Sleep apnea breathing therapy – Masks and application accessories);
- Working pressure test ;
- Filter connection;
- Access to patient for airway management;
- Resistance to flow (resistance Flow): This device has been tested to ISO 17510:2015 Medical devices – Sleep apnea breathing therapy – Masks and application accessories;
- Breathing during single fault condition: This device has been tested to ISO 17510:2015 Medical devices – Sleep apnea breathing therapy – Masks and application accessories;
- Protection against CO_2 rebreathing: This device has been tested to ISO 17510:2015 Medical devices – Sleep apnea breathing therapy – Masks and application accessories;

- Construction Requirements;
- Noise test.

For Biocompatibility, this device has been tested to:

- ISO 10995-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization
- ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation
- ISO 10993-11:2017 Biological evaluation of medical devices Part 11: Tests for system toxicity (pyrogenicity and acute systemic toxicity)
- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds
- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate

Results of the evaluations demonstrate that the subject device meets the safety and performance requirements as per its indication for use.

8. Clinical data

N/A

9. Conclusions

In light of above summarized evidences and based on classification, intended use, technical features and performance data, the subject device is substantially equivalent to the predicate devices.