July 13, 2023

SMD Manufacturing LLC
% Tianna Benson
RAQA Manager
Lean RAQA, LLC
131 E Loch Lomond Dr.
Oro Valley, Arizona 85737

Re: K231064
Trade/Device Name: ReddyPort Elbow
Regulation Number: 21 CFR 868.5895
Regulation Name: Continuous Ventilator
Regulatory Class: Class II
Product Code: MNS
Dated: April 13, 2023
Received: April 14, 2023

Dear Tianna Benson:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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 Sleep Disordered
Breathing, Respiratory and
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OHT1: Office of Ophthalmic, Anesthesia,
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Office of Product Evaluation and Quality
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)*
K231064

Device Name
ReddyPort Elbow

Indications for Use *(Describe)*
The ReddyPort Elbow is intended to provide an interface for application of CPAP or bi-level therapy to the patient including while the patient is simultaneously undergoing another care procedure (e.g. oral care, suctioning, bronchoscopy) by hospital/institutional clinicians. The elbow is for single patient use in the hospital/institutional environment. The elbow is to be used on patients (> 40 lbs/ 18.2 kg) for whom CPAP or bi-level therapy has been prescribed. The elbow can be used with Philips Respironics AF541 masks and AF531 masks with the clip-style connection.

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
K231064

Applicant/Submitter

Company Name	:	SMD MANUFACTURING LLC
Street Address	:	918 S 500 W, Ste A
City	:	Salt Lake City
State	:	UT
Zip Code	:	84101

Contact Person

Full Name	:	Jared Spendlove
Phone	:	(801) 458-1959

Correspondent Information

Full Name	:	Laura Nygard
Phone	:	734-807-1282

Date of Preparation

Date of Preparation	:	07/06/2023

Device Information

Device Information Table

Trade Name	ReddyPort Elbow
Common or Usual Name	Ventilator, Continuous, Non-Life-Supporting
Classfication Name	21 CFR 868.5895 Continuous ventilator.
Regulatory Class	2
Product Code	MNS

Predicate Device(s)

Predicate Device(s) Table

Predicate Type	510(k) Number	Name Of Device	Name Of Manufacturer	Purpose of Reference Device
Primary Device	K171827	ReddyPort NIV Access Elbow	SMD Manufacturing, LLC	N/A - Primary Predicate Device
Reference Device	K150639	AF541 EE Full Face Mask	RESPIRONICS, INC.	The ReddyPort Elbow interfaces with this mask, replacing the AF541 EE elbow, in order to allow patients under CPAP or bi-level therapy to also undergo another care procedure.
Reference Device	K132168	BRONCHOSCOPY ELBOW	RESPIRONICS, INC.	Demonstrate substantial equivalence for the ReddyPort Elbow's use during bronchoscopy indication.

Device Description

The ReddyPort Elbow is an NIV elbow that replaces the elbow on Respironics AF541 style masks and AF531 masks with a clip-style connection and provides oral access for clinicians to the patient's airway during CPAP and bi-level therapy. The ReddyPort Elbow is compatible with both Over the Nose (OTN) cushion ((S, M, L, XL sizes) and an Under the Nose (UTN) cushion (A, B, C sizes) configurations of the AF541 EE Mask and AF531 mask with clip-style connection. ReddyPort permanently replaces the conventional elbow on the mask and maintains positive pressure. This elbow allows for respiratory care procedures (e.g. oral care, suctioning, bronchoscopy) to be performed on a patient while the patient is receiving non-invasive ventilation. The elbow contains a duckbill valve that allows the clinician to access the patient's airway and that seals with similar leak rates to conventional NIV elbows. In addition, the elbow includes an anti-asphyxia valve to ensure safety of the patient.

Intended Use/Indications for Use

The ReddyPort Elbow is intended to provide an interface for application of CPAP or bi-level therapy to the patient including while the patient is simultaneously undergoing another care procedure (e.g. oral care, suctioning, bronchoscopy) by hospital/institutional clinicians. The elbow is for single patient use in the hospital/institutional environment. The elbow is to be used on patients (> 40 lbs/ 18.2 kg) for whom CPAP or bi-level therapy has been prescribed. The elbow can be used with Philips Respironics AF541 masks and AF531 masks with the clip-style connection.

Comparison of Technological Characteristics with Predicate

Substantial Equivalence Comparison Table

Characteristics	Subject Device	Predicate Device	Reference Device	Reference Device	Substantial Equivalence Remarks
Device	ReddyPort Elbow	ReddyPort NIV Access Elbow	AF541 Leak 1 EE Elbow	BRONCHOSCOPY ELBOW	N/A
Manufacturer	SMD Manufacturing, LLC	SMD Manufacturing, LLC.	Respironics, Inc	RESPIRONICS, INC.	N/A
Model	RP-541-L1	RP531	Unknown	Unknown	N/A
510(k) Number	K231064	K171827	K150639	K132168	N/A

Characteristics	Subject Device	Predicate Device	Reference Device	Reference Device	Substantial Equivalence Remarks
Indications for Use	The ReddyPort Elbow is intended to provide an interface for application of CPAP or bi-level therapy to the patient including while the patient is simultaneously undergoing another care procedure (e.g. oral care, suctioning, bronchoscopy) by hospital/institutional clinicians. The elbow is for single patient use in the hospital/institutional environment. The elbow is to be used on patients (> 40 lbs/ 18.2 kg) for whom CPAP or bi-level therapy has been prescribed. The elbow can be used with Philips Respironics AF541 masks and AF531 masks with the clip-style connection.	The ReddyPort NIV Access Elbow is intended to provide an interface for application of CPAP or bi-level therapy.The elbow is for single patient use in the hospital/institutional environment.The elbow is to be used on patients 7 years or older (>40lbs/18.2kg) for whom CPAP or bi-level therapy has been prescribed.	This Mask is intended to provide an interface for application of CPAP or bilevel therapy to patients.The mask is for single use in the hospital/institutional environment only.The mask is to be used on patients (>40lbs/20kg) for whom CPAP or bilevel therapy has been prescribed.	The Bronchoscopy Elbow can be used with Respironics Masks that incorporate the mating elbow hub design. Use of this elbow with these masks allows CPAP and bi-level therapy to be delivered to the patient during a bronchoscopy procedure. The elbow is for single use in the hospital/institutional environment only	Similar
PatientPopulation	Patients (>40lbs/18.2kg)	Patients 7 years or older (>40lbs/18.2kg)	Patients (>40lbs/20kg)	Pediatrics and adults (age >7 years and >40 lbs)	Similar
Environment of Use	Hospital/Institutional Environment Only	Hospital/Institutional Environment Only	Hospital/InstitutionalEnvironment only	Hospital/Institutional Environment Only	Same
Product Code	MNS	MNS	BZD	BZD	Same as predicate
Provided Sterile or Non-Sterile	Provided Non-Sterile (Clean)	Provided Non-Sterile (Clean)	Provided Non-Sterile (Clean)	Provided Non-Sterile (Clean)	Same
Patient Usage Type	Single patient use in the hospital/institutional environment	Single patient use in the hospital/institutional environment	Single patient use in the hospital/institutional environment	Single patient use in the hospital/institutional environment	Same
Design	Permanent replacement elbow with duckbill and anti-asphyxia valve.The RP-541-L1 style has a clip style connection to the mask.	Permanent replacement elbow with duckbill and anti-asphyxia valve.The connection style is a press fit design.	EE Leak 1 Elbow with anti-asphyxia valve.	The Bronchoscopy Elbow is a Leak 1 elbow that attaches to an AF541 mask.It contains an S-slit valve through which a bronchoscopy scope may be inserted to perform a bronchoscopy procedure while a patient is on non-invasive ventilation. The elbow does not contain an anti-asphyxia valve or exhalation ports and is only intended to be used during a bronchoscopy procedure and should be replaced with an EE Elbow after the procedure if the patient is to remain on non-invasive ventilation.	Similar
Valve Type/Size	Duckbill Valve	Duckbill Valve	No access valve is incorporated	Valve for bronchoscopy scope.	Similar

Characteristics	Subject Device	Predicate Device	Reference Device	Reference Device	Substantial Equivalence Remarks
Body Material	Polypropylene	Polycarbonate	Polypropylene	Unknown	Similar
Access Valve Material	Silicone Elastomer	Silicone Elastomer	Does not have an Access Valve feature	Silicone Elastomer	Similar
Anti-Asphyxia Valve Material	Silicone Elastomer	Silicone Elastomer	Silicone Elastomer	N/A	Same
Pick Off Port	N/A	Included	N/A	Included	N/A
Shape and Size	ReddyPort has a streamlined, low dead-space design with a large duckbill valve.	Has a larger overall profile with higher dead-space.	Traditional NIV elbow streamlined, low dead space design	Sizes small and large	Similar
Safety Valve	Includes anti-asphyxia valve	Includes anti-asphyxia valve	Includes anti-asphyxia valve	The bronchoscopy elbow does not have built in exhalation or entrainment valve.	Same
Duration of Replacement	In place for entirety of NIV therapy	In place for entirety of NIV therapy	In place for entirety of NIV therapy	For temporary use during a bronchoscopy procedure	Similar
Intentional vent holes	No vent holes	No vent holes	No vent holes	No vent holes	Same
Pressure Range	4 to 30 cmH2O	4 to 30 cmH20	4 to 30 cmH2O	4 to 30 cmH_2O	Same
Patient Circuit Connection	22mm Connection	22mm connection	22mm Connection	22mm Connection	Same
Elbow Deadspace	37.59 mL	50.9mL	Unknown*	Unknown*	Similar
Leak Rates	4 cmH_2O: 0.6 L/min 10 cmH_2O: 0.65 L/min 17 cmH_2O: 0.89 L/min 24 cmH_2O: 1.11 L/min 30 cmH_2O: 1.34 L/min	4 cmH_2O: 8.46 L/min 10 cmH_2O: 7.26 L/min 17 cmH_2O: 7.65 L/min 24 cmH_2O: 7.56 L/min 30 cmH_2O: 7.35 L/min	Unknown *	Unknown*	Similar
Resistance to Flow During Regular Condition	Added resistance to flow during: 50 L/min flow: 0.23 cmH_2O 100L/min flow: 0.13 cmH_2O	Added resistance to flow during: 50 L/min flow: 0.223 cmH_2O 100 L/min flow: 0.217 cmH_2O	Unknown*	Unknown*	Similar
Resistance Under Single Fault	Added Inspiratory Resistance: 1.23 cmH_2O Added Expiratory Resistance 0.43 cmH_2O	Added Inspiratory Resistance: 0.6 cmH_2O Added Expiratory Resistance 0.5 cmH_2O	Unknown*	Unknown*	Similar

*Data not publicly available.

Performance Testing

The following bench testing was completed for the proposed device:

- ISO 17510:2015 Medical devices -- Sleep apnoea breathing therapy - Masks and application accessories
- ISO 5356-1:2015 Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets
- Mask and Tubing Connection Force
- Dead Space

The ReddyPort Elbow met all applicable requirements and acceptance criteria.

Biocompatibility Testing

The biocompatibility impact of the changes was evaluated in accordance to ISO 10993-1:2018, ISO 18562-1:2017, and FDA Guidance for Industry and Food and Drug Administration Staff "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'" Document issued on September 4, 2020. The battery of testing included:

- ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity carcinogenicity and reproductive toxicity
- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5:Tests for in vitro cytotoxicity
- ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2017 Biological evaluation of medical devices - Part 11:Tests for systemic toxicity
- ISO 10993-17:2002 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
- ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process
- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter
- ISO 18562-4:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate

The device is categorized as an External Communicating Device with Indirect Tissue contact for long-term duration contact (> 30 days).

All biological testing conducted demonstrated passing results (met acceptance criteria) and were conducted on test articles that are representative of the final, finished device in its final, finished form.

Clinical Testing

No clinical testing was conducted as part of this 510(k) submission.

Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the proposed device is as safe, as effective, and performs as well as or better than the legally marketed predicate device.