November 25, 2020

SysMed (China) Co., Ltd
℅ Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O Box 120-119
Shanghai, 200120
China

Re: K192177
Trade/Device Name: SysMed S/T
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: October 29, 2020
Received: October 30, 2020

Dear Diana Hong:

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,

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192177

Device Name
SysMed S/T

Indications for Use *(Describe)*

The device provides positive pressure therapy for the treatment of adult obstructive sleep apnea syndrome in self breathing patients weighing over 30kg (66lbs). This product can be used in the home as well as in clinical/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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K192177

1. Date of Preparation: 11/24/2020

2. Sponsor Identification

SysMed (China) Co., Ltd
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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Ms. Ying Xu (Alternative Contact Person)

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Email: info@mid-link.net

4. Identification of Proposed Device

Trade Name: SysMed S/T
Common Name: Bi-Level S/T

Regulatory Information

Classification Name: ventilator, non-continuous (respirator)
Classification: II;
Product Code: BZD;
Regulation Number: 21CFR 868.5905
Review Panel: Anesthesiology;

Indication for Use Statement:

The device provides positive pressure therapy for the treatment of adult obstructive sleep apnea syndrome in self breathing patients weighing over 30kg (66lbs). This product can be used in the home as well as in clinical/hospital environments.

Device Description

The proposed device is a non-invasive, continuous positive airway pressure ventilator, incorporating a heated respiratory humidifier. The device is intended to treat obstructive sleep apnea by delivering a flow of positive airway pressure at a level prescribed by a physician to splint open the airway and prevent airway collapse.

The proposed device is available in three types, which are Aurora, Resware and Zizmer. Each type is available in different models designed with different therapy modes and pressure ranges. The therapy modes are available in four types, which are CPAP, Spontaneous (S), Spontaneous/Timed (S/T) and Timed (T). The pressure range for the proposed devices is available in three types, which are 4-20cm H_2O, 4-25cm H_2O and 4-30cm H_2O. The designated pressure range and therapy mode for each proposed model was provided in following table

Type	Model	Pressure Range	Operating Mode
Aurora-series	Aurora Bi-Level S	4-25 cm H_2O	CPAP, S
	Aurora Bi-Level S/T	4-25 cm H_2O	CPAP, S, S/T
ZiZmer-series	ZiZ CPAP	4-20 cm H_2O	CPAP
Resware-series	BI 20 S	4-20 cm H_2O	CPAP, S
	BI 20 S/T	4-20 cm H_2O	CPAP, S, S/T, T
	BI 25 S	4-25 cm H_2O	CPAP, S

	BI 25 S/T	4-25 cm H_2O	CPAP, S, S/T, T
	BI 30 S/T	4-30 cm H_2O	CPAP, S, S/T, T

Alarm module is incorporated in the device. The device will generate audio and visual alarm for airway leakage, motor malfunction and high motor temperature.

The proposed device is provided non-sterile, and not to be sterilized by the user prior to use. The proposed device can be reused by single patient.

5. Identification of Predicate Device

510(k) Number: K140159
Product Name: S9 WANDA VPAP ST

6. Identification of Reference Device

510(k) Number: K153061
Product Name: Juno VPAP ST-A

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

- AAMI/ANSI ES60601-1:2005/(R) 2012 And A1:2012, C1:2009/(R) 2012 And A2:2010/(R) 2012 Medical Electrical Equipment-Part 1: General Requirements for Basic Safety and Essential Performance;
- IEC 60601-1-8:2012 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
- IEC 60601-1-11:2015 Medical Electrical Equipment–Part 1-11: General requirements for basic safety and essential performance-Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-2: 2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ISO 80601-2-70:2015 Medical Electrical Equipment-Part 2-70: Particular Requirements for Basic Safety and Essential Performance of Sleep Apnea Breathing Therapy Equipment;
- ISO 80601-2-74:2017 Medical Electrical Equipment-Part 2-74: Particular Requirements for Basic

Safety and Essential Performance of Respiratory Humidifying Equipment;

- ISO 10993-1: 2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- 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: Test for irritation and skin sensitization;
- ISO 10993-12: 2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
- 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 18562-4: 2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate

8. Substantially Equivalent (SE) Comparison

Table 1 Comparison of Technology Characteristics

Item	Proposed Device	Predicate Device K140159	Reference Device K153061
Classification	II	II	II
Product Code	BZD	BZD	MNS
Regulation Number	21 CFR 868.5905	21 CFR 868.5905	21 CFR 868.5895
Intended Use	The device provides positive pressure therapy for the treatment of adult obstructive sleep apnea syndrome in self breathing patients weighing over 30kg (66lbs). This product can be used in the home as well as in clinical/hospital environments.	The S9 WANDA VPAP ST is indicated for the treatment of Obstructive Sleep Apnea (OSA) in patients weighing more than 66lb (30kg). It is intended for use in the hospital and home.	The Juno VPAP ST-A is indicated to provide noninvasive ventilation for patients weighing more than 30lbs (13 kg) with respiratory insufficiency or obstructive sleep apnoea (OSA). The iVAPS mode is indicated for patients weighing more than 66lbs (30 kg). The Juno VPAP ST-A is intended for home and hospital use. The humidifier is intended for single patient use in the home environment and re-use in a hospital/institutional environment.
Environment of Use	Hospital/Home	Hospital/Home	Hospital/Home
Modes Available	CPAP; S; T S/T;	CPAP S T S/T VAuto	CPAP S T S/T PAC iVAPS
Pressure Range	CPAP: 4-20cmH_2O S, S/T, T: 4-30cmH_2O	CPAP: 4-20cmH_2O S, S/T, T: 2-25cmH_2O	CPAP: 4-20cmH_2O S, S/T, T: 3-30cmH_2O
Sterile	Non-sterile	Non-sterile	Non-sterile

Single Use	Reuse	Reuse	Reuse
Prescription status	Prescription	Prescription	Prescription
Supplemental oxygen	No	Labeled for use with Supplemental Oxygen	Labeled for use with Supplemental Oxygen
Alarm	Yes	No	Yes
Wireless	Yes	Yes	Yes
Humidifier	Yes	Yes	Yes
Ramp	User selected as “Off” to 45 minutes in 5 minute increments	User selected as “Off” to 45 minutes in 5 minute increments	User selected as “Off” to 45 minutes in 5 minute increments.
Transmit data	therapy data, therapy settings, upgrade device software	therapy data, therapy settings, upgrade device software	therapy data, therapy settings, upgrade device software
Data transfer medium	SD card, Wireless	SD card, Wireless	SD card, Wireless
Biocompatibility			
Cytotoxicity	Comply with ISO 10993-5	Comply with ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-12 standards	Comply with ISO 10993-1, ISO 10993-5, ISO 10993-10 and ISO 10993-12 standards
Skin Irritation	Comply with ISO 10993-10		
Sensitization	Comply with ISO 10993-10		
Particulate matter	Comply with ISO 18562-2		
Volatile organic compounds (VOCs)	Comply with ISO 18562-3		
Leachables in condensate	Comply with ISO 18562-4		
Electrical Safety and EMC	Comply with IEC 60601-1-8: 2012; AAMI/ANSI ES60601-1:2005/(R) 2012 And A1:2012, C1:2009/(R) 2012 And A2:2010/(R) 2012; IEC 60601-1-2: 2014 IEC 60601-1-11: 2011 ISO 80601-2-70: ISO 80601-2-74	Comply with IEC 60601-1:2005+AMD1: 2012 IEC 60601-1-2:2014 IEC 60601-1-8: 2006 IEC 60601-1-11:2010	Comply with IEC 60601-1:2005+AMD1: 2012 IEC 60601-1-2:2014 IEC 60601-1-8: 2006 IEC 60601-1-11:2010

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.