July 2, 2021

Suzhou Yuyue Medical Technology Co., Ltd.
Sun Wei
R&D engineer
No. 9 Jinfeng Road, Suzhou Science & Technology Town
Suzhou, Jiangsu 215163
China

Re: K203347
Trade/Device Name: Sleep Apnea Breathing Therapy Mask: YF-01 Full Face Mask, YF-02 Full Face Mask, YF-03 Full Face Mask, YN-02 Nasal Mask, YN-03 Nasal Mask, YP-01 Nasal Pillows Mask.
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: May 28, 2021
Received: June 3, 2021

Dear Sun Wei:

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,

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
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)*
K203347

Device Name
Sleep Apnea Breathing Therapy Mask: YF-01 Full Face Mask, YF-02 Full Face Mask, YF-03 Full Face Mask, YN-02 Nasal Mask, YN-03 Nasal Mask, YP-01 Nasal Pillows Mask

Indications for Use *(Describe)*

The sleep apnea breathing therapy mask is a non-invasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bi-level system.

-The mask is to be used by patients (weighing>30kg), intended for single patient reuse in the home environment.
-The mask is intended for single-patient use in the hospital or institutional environment.

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

Company Name/Owner	Suzhou Yuyue Medical Technology Co., Ltd.
Contact person/Author	Sun Wei (Mr.)
Date prepared	06/30/2021
Contact details	Address: No.9 Jinfeng Road, Suzhou Science & Technology Town, 215163 Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA Tel: +86-512-67373001 Fax: +86-512-67373008
Trade name	Sleep Apnea Breathing Therapy Mask: YF-01 Full Face Mask, YF-02 Full Face Mask, YF-03 Full Face Mask, YN-02 Nasal Mask, YN-03 Nasal Mask, YP-01 Nasal Pillows Mask
Common name	Sleep Apnea Breathing Therapy Mask
Classification name	Non Continuous Ventilator (IPPB) Class II (21 CFR §868.5905) Product code BZD (Anaesthesiology)
Predicate device	Full Face Mask: AirFit F20(K170924) Nasal Mask: AirFit N20(K161978) Nasal Pillows Mask: Swift™ FX Nasal Pillows (K090244)

Description

These masks act as an interface for CPAP/BPAP device and deliver pressurized air to prevent apnea from occurring. The masks consist of several parts which includes frame, cushion, elbow, swivel, and headgear. The frame provides support for the mask, the cushion provides the seal, the elbow is designed to provide a vent for exhaust gas and a valve to prevent asphyxiation. The swivel can be rotated 360 degrees, which can help prevent pipe winding. The size of the connector port of the swivel is consistent with ISO standards and can be connected to any tube which conforms to the same standard. The headgear is used to fasten the mask to the face. The masks can be disassembled without any tools.

Indications for use

The sleep apnea breathing therapy mask is a non-invasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bi-level system.

-The mask is to be used by patients (weighing>30kg), intended for single patient reuse in the home environment.
-The mask is intended for single-patient use in the hospital or institutional environment.

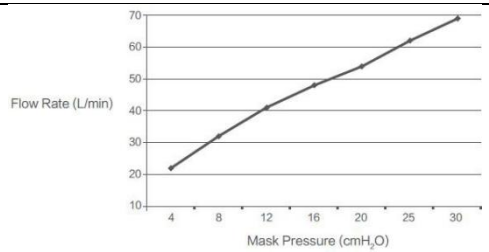
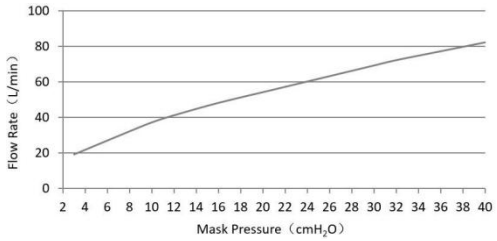
Substantial equivalence comparison with predicate device

Detailed substantial comparison was made between subject device and predicate device. Please refer to below tables for details.

Table 1: Comparison table between full face mask and AirFit F20

Comparison Elements	Subject Device	Predicate Device	Comment
	YF-01 Full Face Mask YF-02 Full Face Mask YF-03 Full Face Mask	AirFit F20	
Classification Regulation	868.5905	868.5905	Identical
Product Code	BZD	BZD	Identical
510(k) Number	K203347	K170924	
Indications for use	The sleep apnea breathing therapy mask is a non-invasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bi-level system. -The mask is to be used by patients (weighing>30kg), intended for single patient reuse in the home environment. -The mask is intended for single-patient use in the hospital or institutional environment.	The AirFit F20 is a non-invasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system. The AirFit F20 is: • to be used by patients weighing more than 66 lb (30 kg) for whom positive airway pressure therapy has been prescribed • intended for single-patient reuse in the home environment and multi-patient reuse in the	Different The inclusion of “single-patient reuse” is a narrower indication to the “multi-patient, multi-use” in the hospital /institutional environment and does not alter the intended use of the device. Safety and effectiveness issue will not be raised.

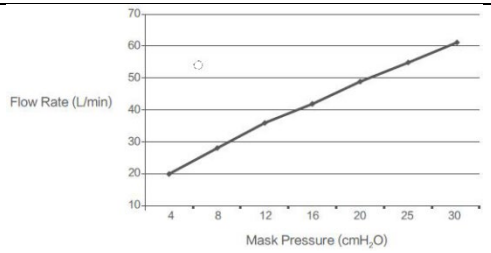
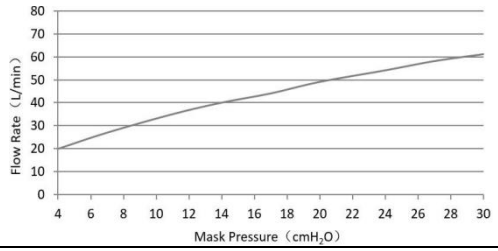
		hospital/institutional environment.	
Principle	Positive airway pressure(PAP)	Positive airway pressure(PAP)	Identical
Patient usage type	single-patient reuse in the home environment. single-patient use in the hospital or institutional environment.	single-patient reuse in the home environment and multi-patient reuse in the hospital/institutional	Different The inclusion of "single-patient reuse" is a narrower indication to the "multi-patient, multi-use" in the hospital/institutional environment and does not alter the intended use of the device. Safety and effectiveness issue will not be raised.
Pressure source action body site	Mouth and Nose	Mouth and Nose	Identical
Technical Specifications			
Breathing Tube connection	22mm conical connector	22mm conical connector	Identical
Pressure Range	4-30 cmH_2o	3-40 cmH_2o	Different Safety and effectiveness issue will not be raised.

Pressure-Flow Cure			Similar, Safety and effectiveness issue will not be raised.
Dead space （largest）	208mL	240mL	Different The dead space of our masks is less than AirFit F20. Both meet relevant standard requirement. Safety and effectiveness issue will not be raised.
Resistance to Flow	at 50 L/min: 0.5 hPa at 100 L/min:1.5 hPa	at 50 L/min: 0.2hPa at 100 L/min:0.6 hPa	Different The Resistance of our mask is higher than AirFit F20. Both meet relevant standard requirement. Safety and effectiveness issue will not be raised.
Inspiratory and expiratory resistance with the Non-Rebreathing Valve open-to-atmosphere	Inspiratory at 50 L/min: ≤2 cmH_2O Expiratory at 50 L/min: ≤2 cmH_2O	Inspiratory at 50 L/min: 0.6 cmH_2O Expiratory at 50 L/min: 0.7 cmH_2O	Different Both meet Clause 2.1 of ISO 17510:2015 which need the pressure is less than 10 cmH_2O. Safety and effectiveness issue will not

pressure			be raised.
Sound	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is less than 38 dBA, with uncertainty 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is less than 30 dBA, with uncertainty 3 dBA.	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 30 dBA, with uncertainty of 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 23 dBA, with uncertainty of 3 dBA.	Different The sound of our masks is more than AirFit F20, but the sound pressure level of our masks is less than 30 dBA, they are quiet and don't interfere with sleep. Safety and effectiveness issue will not be raised.
Operating environment	+5°C to +40°C (41°F to 104°F) 10%～90% relative humidity non-condensing	41°F to 104°F(5°C to +40°C) 15% to 95% non-condensing	Temperature is identical. Humidity is different, but very similar. Safety and effectiveness issue will not be raised.
Storage and transport environment	-20°C to +60°C (-4°F to 140°F) 10%～90% relative humidity non-condensing	-4°F to 140°F (-20°C to +60°C) Up to 95% non-condensing	Temperature is identical. Humidity is different, but very similar. Safety and effectiveness issue will not be raised.

Table2: Comparison table between Nasal mask and AirFit N20

Comparison Elements	Subject Device	Predicate Device	Reference device	Comment
	YN-02 Nasal Mask YN-03 Nasal Mask	AirFit N20	BMC-NM	
Classification Regulation	868.5905	868.5905	868.5905	Identical
Product Code	BZD	BZD	BZD	Identical
510(k) Number	K203347	K161978	K133009	
Indications for use	The sleep apnea breathing therapy mask is a non-invasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bi-level system. -The mask is to be used by patients (weighing>30kg), intended for single patient reuse in the home environment. -The mask is intended for single-patient use in the hospital or institutional environment.	The AirFit N20 channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel device. The AirFit N20 is: • to be used by patients weighing more than 66lb (>30kg) for whom positive airway pressure has been prescribed. • intended for single-patient re-use in the home environment and multi-patient re-use in the hospital/institutional environment	The BMC-NM Nasal Mask channel airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system. The BMC-NM Nasal Mask are: • To be used by adult patients (66lbs/>30kg) for whom positive airway pressure has been prescribed. • Intended for single-patient reuse in home environment and multi-patient re-use in the hospital/institutional environment.	Different The inclusion of "single-patient reuse" is a narrower indication to the "multi-patient, multi-use" in the hospital /institutional environment and does not alter the intended use of the device. Safety and effectiveness issue will not be raised.
Principle	Positive airway pressure(PAP)	Positive airway pressure(PAP)	Positive airway pressure(PAP)	Identical
Patient usage type	single-patient reuse in the home environment. single-patient use in the hospital or institutional environment.	single patient re-use in the home environment and multi-patient re-use in the hospital/institutional	Single-patient reuse in home environment and multi-patient re-use in the hospital/institutional environment.	Different The inclusion of "single-patient reuse" is a narrower indication

		Environment.		to the “multi-patient, multi-use” in the hospital/institutional environment and does not alter the intended use of the device. Safety and effectiveness issue will not be raised.
Pressure source action body site	Nose	Nose	Nose	Identical
Technical Specifications				
Breathing Tube connection	22mm conical connector	22mm conical connector	22mm entrainment valve elbow	Identical
Pressure Range	4-30 cmH_2o	4-30 cmH_2o	4 to 30 hPa	Identical
Pressure-Flow Cure			4hPa=19L/min 12hPa=34L/min 2hPa=50L/min 30hPa=68L/min	Similar Safety and effective-ness issue will not be raised.
Dead space（largest）	142mL	103.3mL	145ml	Different The dead space of our masks is bigger than AirFit N20. Both meet relevant standard requirement. In addition, the dead

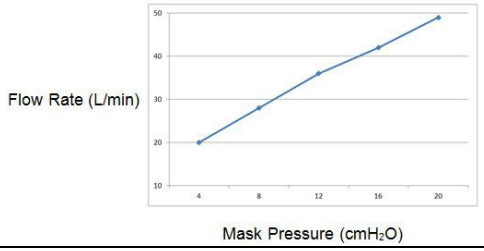
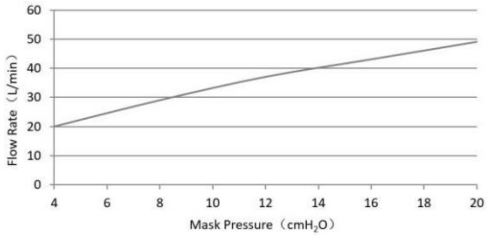
				space of our mask is comparable with that of the reference device. Safety and effectiveness issue will not be raised.

Resistance to Flow	at 50 L/min: 0.5 hPa at 100 L/min:1.5 hPa	at 50 L/min: 0.3 hPa at 100 L/min:1.3 hPa	at 50 L/min: 0.2 hPa at 100 L/min:0.7 hPa	Different The Resistance of our mask is higher than AirFit N20. Both meet relevant standard requirement. Safety and effectiveness issue will not be raised.
Sound	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is less than 38 dBA, with uncertainty 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is less than 30 dBA, with uncertainty 3 dBA.	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 24 dBA, with uncertainty of 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 16 dBA, with uncertainty of 3 dBA.	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is 32 dBA, with uncertainty 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is 24 dBA, with uncertainty 3 dBA.	Different The sound of our masks is more than AirFit N20, but the sound pressure level of our masks is less than 30 dBA, they are quiet and don't interfere with sleep. Safety and effectiveness issue will not be raised.
Operating environment	+5°C to +40°C (41°F to 104°F)	41°F to 104°F (5°C to 40°C)	5 to 40 °C	Temperature is identical. Humidity is different, but very

	10%～90% relative humidity non-condensing	15% to 95% non-condensing	10% to 93% relative humidity non-condensing	similar. Safety and effectiveness issue will not be raised.
Storage and transport environment	-20°C to +60°C (-4°F to 140°F) 10%～90% relative humidity non-condensing	-4°F to +140°(-20°C to +60°C) up to 95% non-condensing	-20 to +55°C 10% to 93% relative humidity, non-condensing	Temperature is identical. Humidity is different, but very similar. Safety and effectiveness issue will not be raised.

Table 3 Comparison Table between Nasal Pillows Mask and Swift™ FX

Comparison Elements	Subject Device	Predicate Device	Comment
	YP-01 Nasal Pillows Mask	Swift™ FX	
Classification Regulation	868.5905	868.5905	Identical
Product Code	BZD	BZD	Identical
510(k) Number	K203347	K090244	
Indications for use	The sleep apnea breathing therapy mask is a non-invasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bi-level system. - The mask is to be used by patients (weighing>30kg), intended for single patient reuse in the home environment. - The mask is intended for single-patient use in the hospital or institutional environment.	The Swift FX channels airflow noninvasively to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel device. The Swift FX is: - to be used by adult patients (>66lb /30kg) for whom positive airway pressure has been prescribed. - intended for single-patient re-use in the home environment and multipatient re-use in the hospital/institutional environment	Different The inclusion of “single-patient reuse” is a narrower indication to the “multi-patient, multi-use” in the hospital /institutional environment and does not alter the intended use of the device. Safety and effectiveness issue will not be raised.

Principle	Positive airway pressure(PAP)	Positive airway pressure(PAP)	Identical
Patient usage type	single-patient reuse in the home environment. single-patient use in the hospital or institutional environment.	single patient re-use in the home environment and multipatient re-use in the hospital/institutional environment	Different The inclusion of "single-patient reuse" is a narrower indication to the "multi-patient, multi-use" in the hospital/institutional environment and does not alter the intended use of the device. Safety and effectiveness issue will not be raised.
Pressure source action body site	Nose	Nose	Identical
Technical Specifications			
Breathing Tube connection	22mm conical connector	22mm conical connector	Identical
Pressure Range	4-20 cmH_2o	4-20 cmH_2o	Identical
Pressure-Flow Cure			Similar Safety and effectiveness issue will not be raised.

Dead space （largest）	16mL	106mL	Different The dead space of our masks is less than Swift™ FX. Both meet relevant standard requirement. Safety and effectiveness issue will not be raised.
Resistance to Flow	at 50 L/min: 1.0 hPa at 100 L/min:3.5 hPa	at 50 L/min: 0.4 hPa at 100 L/min:1.4 hPa	Different The Resistance of our mask is higher than Swift™ FX. Both meet relevant standard requirement. Safety and effectiveness issue will not be raised.
Sound	DECLARED DUAL-NUMBER NOISE EMISSION VALUES in accordance with ISO 4871. The A-weighted sound power level of the mask is less than 38 dBA, with uncertainty 3 dBA. The A-weighted sound pressure level of the mask at a distance of 1 m is less than 30 dBA, with uncertainty 3 dBA.	NA	The sound pressure level of our masks is less than 30 dBA, they are quiet and don't interfere with sleep. Safety and effectiveness issue will not be raised.
Operating environment	+5°C to +40°C (41°F to 104°F) 10%～90% relative humidity non-condensing	+41°F to 104°F (+5°C to +40°C) 15% to 95% relative humidity non-condensing	Temperature is identical. Humidity is different, but Very similar. Safety and effectiveness issue will not be raised.

Storage and transport environment	-20°C to +60°C (-4°F to 140°F) 10%～90% relative humidity non-condensing	-4°F to 140°(-20°C to +60°C) up to 95% relative humidity non-condensing	Temperature is identical. Humidity is different, but Very similar. Safety and effectiveness issue will not be raised.

Non-Clinical Tests

Non-clinical tests were conducted to verify that the subject devices met all design specifications and is substantially equivalent to the predicate. The test results demonstrated that the proposed device complies with the following standards and guidance:

- ISO 17510:2015 Medical devices -- Sleep apnoea breathing therapy -- Masks and application accessories
- ISO 5356-1:2004 Anaesthetic and respiratory equipment - Conical connectors: Part 1: Cones and sockets
- ISO 10993-1:2009 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: Tests for irritation and skin sensitization
- 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 18562-3:2017 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 —Tests for leachables in condensate.
- FDA Guidance: Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, 2015

Conclusion

The sleep apnea breathing therapy masks are substantially equivalent to the predicate devices.