October 29, 2020

Apex Medical Corp.
Chieh Yang
Quality Engineering Manager
No. 9, Min Sheng St. Tu-Cheng.
New Taipei City, 23679 Taiwan

Re: K193206
Trade/Device Name: WiZARD 510 Nasal Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: September 28, 2020
Received: September 30, 2020

Dear Chieh Yang:

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)*
K193206

Device Name
WiZARD 510 Nasal Mask

Indications for Use *(Describe)*
WIZARD 510 Nasal Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. The nasal mask is intended for single-patient reuse in the home and multi-patient, multi-use in the hospital environment. The nasal mask is to be used on patients greater than 30 kg for whom positive airway pressure (CPAP or bi-level system) has been prescribed.

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

Date Prepared: Oct. 24, 2020

Company Name/Owner	APEX Medical Corp. No.9, Min Sheng St., Tu-Cheng, New Taipei City , 23679, Taiwan
Prepared & submitted by	Chieh Yang Quality Engineering Manager TEL: 886-2-2268-5568 #5102 FAX: 886-2-2268-9662 meow.yang@apexmedicalcorp.com
Official Contact	Alan Chang Management Representative APEX Medical Corp. No.9, Min Sheng St., Tu-Cheng, New Taipei City , 23679, Taiwan TEL: 886-2-2268-5568 #6100 FAX: 886-2-2268-9662 alan.chang@apexmedicalcorp.com
Classification Reference	21 CFR 868.5905
Product Code	BZD non-continuous ventilator (Class II)
Common/Usual Name	CPAP Nasal Mask
Proprietary Name	WiZARD 510 Nasal Mask
Legally Marketed Predicate Device	WiZARD 210 Nasal Mask of WiZARD 210/220 Series CPAP Mask (K103174)
Reference Device	WiZARD 310 Nasal Mask of WiZARD 310/320 (K182394)
Indications for use	WIZARD 510 Nasal Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. The nasal mask is

intended for single-patient reuse in the home and multi-patient, multi-use in the hospital environment. The nasal mask is to be used on patients greater than 30 kg for whom positive airway pressure (CPAP or bi-level system) has been prescribed.

Device Description

The WiZARD 510 Nasal Mask provides an interface to direct airflow from a positive pressure source to the patient's nostril. The mask is held in place with adjustable headgear that straps the mask to the face. The elbow connector is designed with a series of vent holes to exhale air from the mask. WiZARD 510 nasal mask is connected to a CPAP or bi-level system via a standard 22 mm breathing tube. A quick release mechanism allows users to quickly remove the mask from the face.

WiZARD 510 Nasal Mask is safe when used under the conditions and purposes as indicated in the labeling provided with the product. WiZARD 510 Nasal Mask is a prescription device supplied in non-sterile condition.

Comparison of subject device to predicate device:

Item	Predicate Device WiZARD 210 Nasal Mask of WiZARD 210/220 Series CPAP Mask (K103174)	Subject Device WiZARD 510 Nasal Mask
Principles of Operation	To provide an interface such that airflow from a positive pressure source is directed to the patient's nostril and is held in place with adjustable headgear that straps the mask to the face.	Same as predicate
Patient Use Type	Adult >30 Kg	Same as predicate

Indication	Obstructive sleep apnea	Same as predicate
Environment	Home, Hospital	Same as predicate
Reuse	Single patient multi-use for home Multi-patient multi-use for hospital	Same as predicate
Patient Support System	CPAP or bi-level system	Same as predicate
Shelf Life	5 years	Same as predicate
Useful Life	6 months	Same as predicate
Mask Size	L/M/S	L/M
Mask Weight	L: 117.3g/M: 115.1g/ S:113.2g	L: 93.5 g/ M: 91.5 g
Mask Dead Space	L: 118ml/ M:107ml/S:89ml	L:93.6ml/ M: 75.3ml
Sterility	Clean, non-sterile	Same as predicate
Validated Cleaning	Warm water	Same as predicate
Validated Disinfection	Thermal water/High level chemical disinfectant	Same as predicate
Therapy Pressure Range	4~20 cmH_2O	4~30 cmH_2O
Exhalation holes location	On the elbow assembly	Same as predicate
Hose Connection	22 mm hose	Same as predicate
CPAP Tubing connection point	A port compliance to ISO 5356-1 is used to connect to CPAP delivery hose	Same as predicate
Swivel Connection	360 degree rotation	Same as predicate

Secure and Less-leak Interface	Single layer cushion	Same as predicate
Operation Range	+5℃ to +35℃ (+41℉ to +95 ℉) 15% to 95% R.H (non-condensing)	Same as predicate
Storage and Transport	-15℃ to +60℃ (+5℉ to +140 ℉) 10% to 90% R.H (non-condensing)	Same as predicate
Component	**Material**	**Material**
Mask Frame	Polycarbonate(PC)	Polycarbonate(PC)
Mask Cushion	2 pcs design: -1pc Polycarbonate(PC) -1pc Silicone (face contact side)	1pc design: - Silicone (face contact side) mounted on Polycarbonate(PC)
Forehead Support Pad	Silicone rubber	NA
Elbow	Polycarbonate(PC)	Same as predicate
Swivel Hose	Polycarbonate(PC)	Same as predicate
Flexible Tube	Silicon Rubber	Low Density Polyethylene (LDPE) Helix / Thermoplastic Elastomer (TPE) FlexFilm™
Tubing Connector	Polypropylene(PP)	Polycarbonate(PC)
Quick Release Button (Buckle)	Polyoxymethylene (POM)	Same as predicate
Headgear Strap	PU Foam/Nylon /Neoprene	PU Foam/Nylon/Polyester
Noise (dB)	<40dB	≦26 dBA (with CAPA

		and humidifier) / ≦28 dBA (with CPAP)
Biocompatibility Test	ISO 10993-1 ISO 10993-5 ISO 10993-10	ISO 10993-1 ISO 10993-5 ISO 10993-10 ISO 10993-17 ISO 10993-18 ISO 18562-1 ISO 18562-2 ISO 18562-3

Comparison of subject device to reference device:

The therapy pressure range of the subject device WiZARD 510 Nasal Mask is expanded to 4~30 cmH_2O and is substantially equivalent to the reference device WiZARD 310 Nasal Mask of WiZARD 310/320 (K182394). Please refer to the following Product Specification Comparison Table:

No	Item	**Reference Device**	**Subject Device**
1	Trade Name	APEX Medical , WiZARD 310 Nasal Mask (K182394)	APEX Medical, **WiZARD 510 Nasal Mask**
2	Product Code	BZD	same as reference devices
3	Regulation Number	868.5905	same as reference devices
4	Regulation Name	CPAP Mask	same as reference devices
5	Indications for use	WIZARD 310/320 series CPAP Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. These masks are intended for single-patient reuse in the home and multi-patient,	WIZARD 510 Nasal Mask is intended to provide an interface for Continuous Positive Airway Pressure (CPAP) or bi-level therapy. The mask is intended for single-patient reuse in the home and

		multi-use in the hospital environment. These masks are to be used on patients greater than 30 kg for whom positive airway pressure (CPAP or bi-level system) has been prescribed.	multi-patient, multi-use in the hospital environment. The mask is to be used on adult patients greater than 30 kg for whom positive airway pressure (CPAP or bi-level system) has been prescribed.
6	Patient Use Type	Adult >30 Kg	same as reference devices
7	Indication	Obstructive sleep apnea	same as reference devices
8	Environment	home, hospital	same as reference devices
9	Reuse	Single patient multi-use for home Multi-patient multi-use for hospital	same as reference devices
10	Patient Support System	CPAP or bi-level system	same as reference devices
11	Principle of Operation	Mask provides an interface such that airflow from a positive pressure source is directed to the patient's nostril and is held in place with adjustable headgear that straps the mask to the face.	same as reference devices
12	Shelf Life	5 years	same as reference devices
13	Useful Life	6 months	same as reference devices
14	Sterility	Clean, non-sterile	same as reference devices
15	Therapy Pressure Range	4~30 cmH_2O	same as reference devices

16	Exhalation Hole	Yes	same as reference devices
17	Hose Connection	22 mm hose	same as reference devices
18	Operation Range	+5℃ to +35℃ (+41℉ to +95℉) 15% to 95% R.H (non-condensing)	same as reference devices
19	Storage and Transport	-15℃ to +60℃ (+5℉ to +140℉) 10% to 90% R.H (non-condensing)	same as reference devices
20	Noise (dB)	≦30dB	≦26 dB (with CPAP and Humidifier) ≦28 dB (with CPAP)

Changes from the predicate devices WiZARD 210 Nasal Mask of WiZARD 210/220 Series CPAP Mask (K103174):

- mechanical design of the mask frame and removal of the forehead support pad.
- materials of the flexible tube, tubing connector and headgear strap.
- color, shape and length of the flexible tube and headgear strap.
- Expansion of the therapy pressure range
- mask size category

Non-clinical data

Non-clinical verification and validation testing completed for the subjected device demonstrated that the WiZARD 510 Nasal Mask met all intended performance requirements. These included:

a. Biocompatibility Test:

- 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, Third Edition Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization

- ISO 10993-17:2002 Biological evaluation of medical devices -- Part 17: Establishment of allowable limits for leachable substances

- ISO 10993-18:2002 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 18562-3: 2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications -- Part 3: Tests for emissions of volatile organic compounds (VOCs)

b. Reliability Test:

- ISO 17510: 2015 Medical devices -- Sleep apnoea breathing therapy -- Masks and application accessories

- Mechanical integrity performance following relevant environmental exposure: home cleaning, transportation and storage, operational temperature and humidity range, drop test, sit test and shelf life.

c. Risk Assessment:

- ISO 14971:2007 Second Edition, Medical devices - Application of risk management to medical devices

d. Reprocessing test

Validation of reprocessing claims included a combination of cleaning

efficacy, disinfection efficacy and mechanical integrity testing.

The above testing confirmed that the WiZARD 510 Nasal Mask met the predetermined acceptance criteria and the performance is substantially equivalent to the previously cleared predicate WiZARD 210 Nasal Mask (K103174).

Conclusion

The subject device WiZARD 510 Nasal mask is substantially equivalent to the predicate device WiZARD 210 Nasal mask of WiZARD 210/220 series CPAP mask (K103174).