May 17, 2019

Apex Medical Corp.
Frank Lin
Management Representative
No. 9 Min Sheng St. Tu-Cheng
New Taipei City, 23679
Taiwan

Re: K182394
Trade/Device Name: WiZARD 310/320 Series CPAP Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: April 17, 2019
Received: April 18, 2019

Dear Frank Lin:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Michael Ryan
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)*
K182394

Device Name
WiZARD 310/320 Series CPAP Mask

Indications for Use *(Describe)*
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, 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Date Prepared: May. 17, 2019

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	Frank Lin Management Representative APEX Medical Corp. No.9, Min Sheng St., Tu-Cheng, New Taipei City , 23679, Taiwan TEL: 886-2-2268-5568 #5001 FAX: 886-2-2268-9662 frank.lin@apexmedicalcorp.com
Classification Reference	21 CFR 868.5905
Product Code	BZD non-continuous ventilator (Class II)
Common/Usual Name	CPAP Mask
Proprietary Name	WiZARD 310/320 Series CPAP Mask
Legally Marketed Predicate Device	WiZARD 210/220 Series CPAP Mask (K103174)
Reference Device	AirFit F20 (K170924) AirFit N20 (K171212)
Intended Use/Indications for	WIZARD 310/320 series CPAP Mask is intended to provide an interface for Continuous Positive Airway

use	Pressure (CPAP) or bi-level therapy. These masks are intended for single-patient reuse in the home and multi-patient, 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.
Patient Population	Adults with OSA
Environment of Use	Hospital, home
Contraindication	This mask is not for use on patients with the following conditions: recent eye surgery or dry eyes, hiatal hernia, excessive reflux, impaired cough reflex, and impaired cardiac sphincter function. This mask is not for use on patients who are dependent on mechanical ventilation for their life support. This mask is not for use on patient who are taking a prescription drug that induces vomiting, or on patients who are uncooperative, unresponsive or unable to remove the mask by themselves. This mask should not be placed over open wound or skin under risk of decubitus ulcers that are prone to infection.
Device Description	The WiZARD 310 Nasal Mask and WiZARD 320 Full Face Mask provide an interface such that airflow from a positive pressure source is directed to the patient's nostril and mouth. The masks are held in place with adjustable headgear that straps the mask to the face. Series of vent are feature on the cushion that serves as an exhalation vent to purge the exhaled carbon dioxide from the mask. Air coming out from these holes is very diffuse and quiet. WiZARD 310/320 series CPAP mask are connected to the CPAP or bi-level system via standard 22 mm breathing tubing. A quickly-release mechanism also includes which allow the mask can be removed quickly. The WiZARD 310 Nasal Mask and WiZARD 320 Full Face Mask are appropriate when used under the conditions and purposes intended as indicated in the labeling provided with the product. The WiZARD 310 Nasal Mask and WiZARD 320 Full Face Mask are the prescription device supplied non-sterile.

Comparison of device to predicate device:

a. Product Specification Comparison Table of Subject Device WiZARD 310/320 Series CPAP Mask, and Predicate Device WiZARD 210/220 Series CPAP Mask (K103174).

Item	Predicate Device WiZARD 210/220 Series CPAP Mask (K103174)			Subject Device WiZARD 310/320 Series CPAP Mask		
Principles of Operation	To provide an interface such that airflow from a positive pressure source is directed to the patient's nostril and mouth and are held in place with adjustable headgear that straps the mask to the face.			Same as left		
Patient Use Type	Adult >30 Kg			Same as left		
Indication	Obstructive sleep apnea			Same as left		
Environment	Home, Hospital			Same as left		
Reuse	Single patient multi-use for home Multi-patient multi-use for hospital			Same as left		
Patient Support System	CPAP or bi-level system			Same as left		
Shelf Life	5 years			Same as left		
Use of Life	6 months			Same as left		
Mask Size	L/M/S			Same as left		
Mask Weight	**(g)**	**210**	**220**	**(g)**	**310**	**320**
	L	117.3	160.1	L	88.57	119.6
	M	115.1	153.7	M	87.41	112.55

	S	113.2	148.5	S	85.83	108.06
Mask Dead Space	**(ml)**	**210**	**220**	**(ml)**	**310**	**320**
	L	118	212	L	112.2	328
	M	107	197	M	96.6	284
	S	89	164	S	76.6	224.8
Sterility	Clean, non-sterile			Same as left		
Validated Cleaning	Warm water			Same as left		
Validated Disinfection	Thermal water/High level chemical disinfectant			Same as left		
Therapy Pressure Range	4~20 cmH_2O			WiZARD 310: 4~30 cmH2O WiZARD 320: 4~40 cmH2O		
Exhalation holes location	On the elbow assembly			On the cushion assembly		
Hose Connection	22 mm hose			Same as left		
CPAP Tubing connection point	A port compliance to ISO 5356-1 is used to connect to CPAP delivery hose			Same as left		
Swivel Connection	360 degree rotation			Same as left		
Secure and Less-leak Interface	Single layer cushion			Same as left		
Operation Range	+5℃ to +35℃ (+41℉ to +95℉) 15% to 95% R.H (non-condensing)			Same as left		
Storage and	-15℃ to +60℃ (+5℉ to +140℉)			Same as left		

Transport	10% to 90% R.H (non-condensing)	
Component	**Material**	**Material**
Mask Frame	PC	TPEE
Mask Cushion	2 pcs design: -1pc PC -1pc Silicone (face contact side)	1pc design: - Silicone (face contact side) mounted on PC
Forehead Support Pad	Silicone rubber	NA
Elbow	PC	Same as left
Elbow Diaphragm	Silicone Rubber (WiZARD 210 without)	Same as left
Port Cap	Silicone rubber	NA
Swivel Hose	PC	Same as left
Silicon Tubing	Silicon Rubber	Same as left
Tubing Connector	PP	Same as left
Quick Release Button (Buckle)	POM	Same as left
Headgear Strap	PU Foam/Nylon /Neoprene (Color : Dark Grey/Black)	PU Foam/Nylon /Neoprene (Color : Light Grey)
Noise (dB)	<40dB	<30dB
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

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

- Chang the material of the mask frame.
- Change the colour and shape of the headgear strap.
- Delete the design of the forehead support pad.

As the table list above shows WiZARD 310/320 Series CPAP Mask incorporates features from predicate device, the subject and predicate device have an identical intended use, patient population, principle of operation, employ same technology with similar performance and made of similar materials.

The main differences between the subject device and the previously cleared predicate device WiZARD 210/220 Series CPAP Mask (K103174) do not affect the substantial equivalence claim to the predicate device because non-clinical testing demonstrated that the new device has equivalent performance to the predicate device.

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 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. Usability Validation:

- IEC 62366-1:2015 Medical devices -- Part 1: Application of usability engineering to medical devices

Substantial Equivalence Conclusion

The subject device WiZARD 310/320 series CPAP mask is substantially equivalent to the predicate device WiZARD 210/220 series CPAP mask (K103174):

- It has the same intended use
- It has similar technological characteristics
- It has similar performance characteristics
- The difference do not raise any new questions of safety or effectiveness