May 23, 2025

Wellell Inc.
Chieh Yang
Quality Engineering Manager
No. 9, Min Sheng St.,
Tu-Cheng, New Tapei City, Taiwan
New Taipei City, 236044
Taiwan

Re: K243023
Trade/Device Name: WiZARD 520 Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: September 27, 2024
Received: April 21, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243023

Device Name
WiZARD 520 Full Face Mask

Indications for Use *(Describe)*
The 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-patient multi-use in the hospital environment.

The Mask is to be used by adults weighing ≥ 30 kg 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.

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"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

1. Type of submission: Traditional

2. Date of summary: May 22, 2025

3. Submitter:

Submitter:	Wellell Inc.
Address:	No. 9, Min Sheng St., Tu-Cheng, New Taipei City, 236044, Taiwan
Phone:	+886-2-2268-5568
Fax:	+886-2-2268-9662
Contact:	Chieh Yang (meow.yang@wellell.com)
Job title:	Quality Engineering Manager

4. Identification of the device:

Proprietary/Trade name:	WiZARD 520 Full Face Mask
Classification product Code:	BZD
Regulation number:	21 CFR 868.5905
Regulation description:	Noncontinuous ventilator
Review panel:	Anesthesiology
Device class:	II

5. Identification of the Predicate Device:

Predicate device name:	WiZARD 310/320 Series CPAP Mask
Manufacturer:	Wellell Inc.
Classification product code:	BZD
Regulation number:	21 CFR 868.5905
Device class:	II
510(k) number:	K182394

6. Device description

WiZARD 520 Full Face Mask's cushion and frame provide a secure interface between the mask and the patient's face and the flexible cushion improves seal. A series of vents on the elbow, serve as an exhalation vent to purge the exhaled carbon dioxide from the mask. The mask is designed to maintain a continuous airflow to minimize the amount of CO_2 rebreathed by the patient. The mask features a wider visibility design that ensures a clear line of sight. It also includes a fabric frame equipped with 3D-shaped headgear for enhanced comfort and stability.

WiZARD 520 Full Face Mask is intended for connection to a positive air pressure source such as CPAP or bi-level for the treatment of Obstructive Sleep Apnea.

WiZARD 520 Full Face Mask can be linked to the CPAP or bi-level system's standard 22 mm breathing tube using a swivel hose, flexible tube, and tubing connector. Various sizes (small, medium, and large) are offered to ensure adequate fit over the extended patient population.

7. Indication for use

The 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-patient multi-use in the hospital environment.

The Mask is to be used by adults weighing ≥ 30kgs whom positive airway pressure (CPAP or bi-level system) has been prescribed.

8. **Comparison of technological characteristics with the predicate device**

Characteristic	**Predicate Device** WiZARD 320 CPAP Mask	**Subject Device** WiZARD 520 Full Face Mask	**Comments**
Product Code	BZD	BZD	Equivalent
Regulation Number	868.5905	868.5905	Equivalent
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, 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.	The 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-patient multi-use in the hospital environment. The Mask is to be used by adults weighing ≥ 30 kgs whom positive airway pressure (CPAP or bi-level system) has been prescribed.	Equivalent
Patient Use Type	Adult ≥ 30 kg	Adult ≥ 30 kg	Equivalent
Indication	Obstructive sleep apnea	Obstructive sleep apnea	Equivalent
Environment	Home, hospital	Home, hospital	Equivalent

Characteristic	Predicate Device WiZARD 320 CPAP Mask	Subject Device WiZARD 520 Full Face Mask	Comments
Reprocessing	Single patient reuse or multi-patient reuse	Single patient reuse or multi-patient reuse	Equivalent
Patient Support System	CPAP or bi-level system	CPAP or bi-level system	Equivalent
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.	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.	Equivalent
Use Life	6 months after unpacking	6 months after unpacking (or 30 cycles under disinfection)	The subject device claims to incorporate disinfection considerations.
Mask Size	L/M/S	L/M/S	Equivalent
Mask Dead Space	L: 328 ml M: 284 ml S: 223.8 ml	L: 271 ml M: 228 ml S: 211 ml	Measured dead space is disclosed in labelling in accordance with ISO 17510:2015.
Sterility	Non-sterile	Non-sterile	Equivalent
Pressure Range	4~40 cmH_2O	4~40 cmH_2O	Equivalent
Hose Connection	22 mm	22 mm	Equivalent
Operation Range	+5℃ to +35℃ (+41°F to +95°F) 15% to 95% R.H (non-condensing)	+5℃ to +35℃ (+41°F to +95°F) 15% to 95% R.H (non-condensing)	Equivalent

<table>
<tr><th>Characteristic</th><th colspan="2">Predicate Device
WiZARD 320 CPAP Mask</th><th colspan="2">Subject Device
WiZARD 520 Full Face Mask</th><th>Comments</th></tr>
<tr><td>Storage and Transport</td><td colspan="2">-15℃ to +60℃
(+5°F to +140°F)
10% to 90% R.H (non-condensing)</td><td colspan="2">-15℃ to +60℃
(+5°F to +140°F)
10% to 90% R.H (non-condensing)</td><td>Equivalent</td></tr>
<tr><td rowspan="14">Exhaust Flow</td><td>Pressure (cmH_2O)</td><td>Flow (l/min)</td><td>Pressure (cmH_2O)</td><td>Flow (l/min)</td><td rowspan="14">Testing and reporting have been conducted in line with ISO17510: 2015.</td></tr>
<tr><td>4</td><td>18</td><td>4</td><td>18</td></tr>
<tr><td>8</td><td>26</td><td>13</td><td>35</td></tr>
<tr><td>12</td><td>32</td><td>22</td><td>48</td></tr>
<tr><td>16</td><td>38</td><td>31</td><td>59</td></tr>
<tr><td>20</td><td>45</td><td>40</td><td>69</td></tr>
<tr><td>24</td><td>49</td><td colspan="2" rowspan="8"></td></tr>
<tr><td>28</td><td>53</td></tr>
<tr><td>30</td><td>57</td></tr>
<tr><td>32</td><td>59</td></tr>
<tr><td>36</td><td>63</td></tr>
<tr><td>40</td><td>66</td></tr>
<tr><td rowspan="4">CO_2 Rebreathing Normal condition</td><td>Pressure (cmH_2O)</td><td>Relative CO_2 increase</td><td>Pressure (cmH_2O)</td><td>Relative CO_2 increase</td><td rowspan="4">Equivalent
Complies with ISO 17510:2015 CO_2 requirements (<20%)</td></tr>
<tr><td>4</td><td>16%</td><td>4</td><td>6%</td></tr>
<tr><td>5</td><td>14%</td><td>5</td><td>5%</td></tr>
<tr><td>10</td><td>6%</td><td>10</td><td>1%</td></tr>
<tr><td rowspan="3">CO_2 Rebreathing Single Fault use</td><td>Fault</td><td>Relative CO_2 increase</td><td>Fault</td><td>Relative CO_2 increase</td><td rowspan="3">Equivalent
Complies with ISO 17510:2015 CO_2 requirements (<60%)</td></tr>
<tr><td>Fault 1</td><td>46%</td><td>Fault 1</td><td>41%</td></tr>
<tr><td>Fault 2</td><td>50%</td><td>Fault 2</td><td>39%</td></tr>
</table>

Characteristic	**Predicate Device** WiZARD 320 CPAP Mask		**Subject Device** WiZARD 520 Full Face Mask		**Comments**
Resistance (Pressure Drop)	Flow (l/min)	Pressure (cmH_2O)	Flow (l/min)	Pressure (cmH_2O)	Equivalent
	50	1.0	50	≤ 1.0	
	100	2.0	100	≤ 2.0	
Anti-asphyxia Valve Pressure (cmH_2O)	open-to-atmosphere	0.54	open-to-atmosphere	< 1.5	The AAV pressure are complied with ISO17510: 2015.
	closed-to-atmosphere	0.81	closed-to-atmosphere	< 2.5	
Single-Fault Inspiration/ Specification of Expiration Resistance	Inspiration	0.9	Inspiration	≤ 1.5	The resistance is complied with ISO17510: 2015.
	Expiration	1.0	Expiration	≤ 2.2	
Sound	≤ 30dB		Sound Pressure Level ≤ 26 dBA Sound Power Level ≤ 35 dBA		Measured sound power level is disclosed in labelling in accordance with ISO 17510:2015.

9. Non-clinical testing

The following tests were conducted to evaluate the safety and effectiveness of WiZARD 520 Full Face Mask in accordance with relevant FDA consensus standards including ISO 17510:2015, ISO 10993-1: 2018, ISO 18562-1:2017 and ISO 5356-1:2015.

- Performance test
  - CO_2 Rebreathing
  - Pressure-Flow characteristics
  - Resistance to flow
  - Anti-Asphyxia valve operating pressures
  - Sound power level test
  - Sound pressure level test
  - Dead space test
- Biocompatibility Test
  - Cytotoxicity Test
  - Skin irritation Test
  - Skin sensitization Test
  - Leachable and extractable Test
  - Particulate matter (PM) Test
  - Volatile organic compounds (VOC) Test
- Reliability Test
  - Shipping test
  - Drop test
  - Temperature operation test
  - Sit test
  - Shelf life test report
  - Disinfection validation
  - Cleaning validation

Standards	Title
ISO 17510:2015	Medical devices -- Sleep apnoea breathing therapy -- Masks and application accessories
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: Tests for irritation and skin sensitization
ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
ISO 10993-17:2023	Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents
ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process.
ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
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
IEC 62366-1:2015+AMD1:2020	Medical devices Part 1: Application of usability engineering to medical devices including Amendment 1
ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO 5356-1:2015	Anaesthetic and respiratory equipment — Conical connectors Part 1: Cones and sockets

10. Conclusion

Based on the comparison of characteristics and analysis of non-clinical performance data, we conclude that the WiZARD 520 Full Face Mask is substantially equivalent to the legally marketed predicate device.