May 21, 2026

DCStar Inc.
Emma Chen
Regulatory Affairs Specialist
228 Park Ave S 30327
New York, New York 10003

Re: K251920
Trade/Device Name: Sleep Apnea Breathing Therapy Mask: JoyMask 20-B Full Face Mask, JoyMask 21-B Full Face Mask
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: April 16, 2026
Received: April 16, 2026

Dear Emma Chen:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

For

Rachana Visaria
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)*
K251920

Device Name
Sleep Apnea Breathing Therapy Mask:Joymask 20-B, Joymask 21-B

Indications for Use *(Describe)*
The sleep apnea breathing therapy mask is a non-invasive accessory used for channeling airflow 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.

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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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR 807.92.

Type of submission

Traditional

Date prepared

5/21/2026

Submitter's Information

Company: DCSTAR INC

Address: 228 PARK AVE S 30327, NEW YORK, NY, UNITED STATES, 10003

Submitter: Emma Chen

Telephone: +1 (650) 672-9428

Email: compliance@complianceglobe.com

Device Information

Device name: JoyMask 20-B Full Face Mask, JoyMask 21-B Full Face Mask

Classification name: Non Continuous Ventilator (IPPB)

Production code: BZD

Regulation number: 21 CFR 868.5905

Classification: Class II

Predicate Device Information

510(k) Number: K241830

Manufacturer: Sleepnet Corporation

Device Name: Innova Full Face Vented Mask

Device Class: Class II

Product Code: BZD

Reference Device Information

510(k) Number: K212371

Manufacturer: Fisher & Paykel Healthcare Ltd

Device Name: F&P Evora Full Face Mask

Device Class: Class II

Product Code: BZD

Indications for use

The sleep apnea breathing therapy mask is a non-invasive accessory used for channeling airflow 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.

Device Description

JoyMask 20-B and JoyMask 21-B are full face masks designed to cover the patient's entire mouth and nose, delivering therapeutic pressure through both airways. Each model comprises four main components: a cushion, frame, elbow, and headgear.

The headgear connects to the frame via a plastic clip, securing the cushion in place. The cushion ensures an airtight seal for effective airflow delivery, while the elbow serves as the conduit for the airflow itself.

Substantial Equivalence Table

Table 1 Substantial Equivalence Comparison

Item	Subject Device	Predicate Device	Reference Device	Remark
Device	Sleep Apnea Breathing Therapy Mask - JoyMask 20-B and JoyMask 21-B	Innova Full Face Vented Mask	F&P Evora Full Face Mask	-
Product Code	BZD	BZD	BZD	Same
Regulation No.	21 CFR 868.5905	21 CFR 868.5905	21 CFR 868.5905	Same
Indication for Use	The sleep apnea breathing therapy mask is a non-invasive accessory used for channeling airflow 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 > 30 kg), intended for single-patient reuse in the home environment.	Innova Full Face Vented Mask is intended to be used with positive airway pressure devices, such as CPAP or bilevel, operating at or above 3 cm H2O. The masks are to be used on adult patients (>30kg) for whom positive airway pressure therapy has been prescribed. Single patient, multi-use in the home or hospital/institutional environment.	The F&P Evora Full Face mask is intended to be used by adults weighing ≥ 66lbs (30kgs) who have been diagnosed by a physician as requiring CPAP or Bi-Level therapy. The F&P Evora Full Face mask is intended for single patient use in the home and for multiple patient use in the hospital or other clinical setting where proper disinfection of the device can occur between patient uses.	Equivalent to predicate device
Population	Used on adult patients (>30kg) requiring positive airway pressure therapy.	Used on adult patients (>30kg) requiring positive airway pressure therapy.	Used on adult patients (≥30kg) requiring positive airway pressure therapy.	Equivalent to predicate device
Duration and Environment of Use	Single-patient, multi-use in the home environment.	Single patient, multi-use in the home or hospital/institutional environment.	Single patient use in the home Multiple patient use in the hospital or other clinical setting	Equivalent to predicate device
Prescription for Use	Yes	Yes	Yes	Same
Principle of Operation	Provides a seal over the face (nose and mouth) to allow for delivery of pressurized air from a positive pressure	Provides a seal over the face (nose and mouth) to allow for delivery of pressurized air from a positive	Provides a seal over the face (nose and mouth) to allow for delivery of pressurized air from a positive pressure	Same

<table>
<tr><td></td><td>device such as CPAP or bilevel device. Mask includes an exhalation port and AAV for flushing out exhaled CO2.</td><td>pressure device such as CPAP or bilevel device. Mask includes an exhalation port and AAV for flushing out exhaled CO2.</td><td>device such as CPAP or bilevel device. Mask includes an exhalation port and AAV for flushing out exhaled CO2.</td><td></td></tr>
<tr><td>Non-sterile</td><td>Yes</td><td>Yes</td><td>Yes</td><td>Same</td></tr>
<tr><td>Available Size</td><td>S, M, L</td><td>S, M, L</td><td>XS, S-M, L</td><td>Equivalent to predicate device</td></tr>
<tr><td colspan="4">Technical Specifications</td><td></td></tr>
<tr><td>User Interface to administer therapy</td><td>22mm conical connector (compliant with ISO 5356-1)</td><td>22mm conical connector (compliant with ISO 5356-1)</td><td>22mm conical connector (compliant with ISO 5356-1)</td><td>Same</td></tr>
<tr><td>Dead Space</td><td><table><tr><th>Size</th><th>Dead Space (ml)</th></tr><tr><td>Small</td><td>175.6</td></tr><tr><td>Medium</td><td>188.6</td></tr><tr><td>Large</td><td>210.3</td></tr></table></td><td><table><tr><th>Size</th><th>Dead Space (ml)</th></tr><tr><td>Small</td><td>155.3</td></tr><tr><td>Medium</td><td>181.7</td></tr><tr><td>Large</td><td>196.6</td></tr></table></td><td><table><tr><th>Size</th><th>Dead Space (ml)</th></tr><tr><td>Extra Small</td><td>165.2</td></tr><tr><td>Small-Medium</td><td>162.6</td></tr><tr><td>Large</td><td>164.1</td></tr></table></td><td>Similar to predicate device The dead space are detailed in the IFU.</td></tr>
<tr><td>Pressure Range</td><td>4 to 30 cmH_2O</td><td>3 to 20 cmH_2O</td><td>4 to 30 cmH_2O</td><td>Identical to reference device The pressure range, along with other technical specifications such as exhaust flow characteristics, is detailed in the IFU as a reference for clinicians. The difference from the predicate device do not introduce additional risks.</td></tr>
<tr><td>Therapy Pressure and its exhaust flow characteristics</td><td><table><tr><th>Pressure (cmH_2O)</th><th>Flow (lpm)</th></tr><tr><td>4</td><td>20.6</td></tr><tr><td>11</td><td>37.0</td></tr><tr><td>17</td><td>49.4</td></tr><tr><td>24</td><td>60.9</td></tr></table></td><td><table><tr><th>Pressure (cmH_2O)</th><th>Flow (lpm)</th></tr><tr><td>3</td><td>22.08</td></tr><tr><td>10</td><td>38.50</td></tr><tr><td>20</td><td>54.30</td></tr></table></td><td>Not Publicly Available</td><td>Similar to predicate device In accordance with ISO 17510, the therapy pressure and exhaust flow characteristics are detailed in</td></tr>
</table>

<table>
<tr><td></td><td><table><tr><td>30</td><td>67.8</td></tr></table></td><td></td><td></td><td>the IFU as a reference for the clinicians.</td></tr>
<tr><td>AAV Opening/Closing Pressure</td><td>Opening – 1.89 cmH2O
Closing – 2.22 cmH2O</td><td>Opening – 2.10 cmH_2O
Closing – 2.28 cmH_2O</td><td>Not Publicly Available</td><td>Similar to predicate device
Meet the acceptance criteria as per ISO 17510 (< 4 cmH_2O).
The AAV Opening/Closing Pressure are detailed in the IFU as a reference for the clinicians.</td></tr>
<tr><td>Resistance to Flow</td><td>50 lpm – 0.48 cmH_2O
100 lpm – 0.78 cmH_2O</td><td>50 lpm – 0.07 cmH_2O
100 lpm – 0.39 cmH_2O</td><td>50 lpm – 0.9 ± 0.3 cm H2O
100 lpm – 2.2 ± 0.3cm H2O</td><td>Similar to predicate device
In accordance with ISO 17510, the resistance values are detailed in the IFU as a reference for the clinicians.</td></tr>
<tr><td>Magnet</td><td>No Magnet</td><td>No Magnet</td><td>No Magnet</td><td>Same</td></tr>
<tr><td>CO2 re- breathing performance</td><td><table><tr><th>Setting</th><th>Relative CO2 increase</th></tr><tr><td>4 cmH_2O</td><td>11.6%</td></tr><tr><td>5 cmH_2O</td><td>9.4%</td></tr><tr><td>10 cmH_2O</td><td>5.0%</td></tr><tr><td>Single Fault1</td><td>23.9%</td></tr><tr><td>Single Fault2</td><td>30.7%</td></tr></table></td><td><table><tr><th>Setting</th><th>Relative CO2 increase</th></tr><tr><td>3 cmH_2O</td><td>16%</td></tr><tr><td>5 cmH_2O</td><td>16%</td></tr><tr><td>10 cmH_2O</td><td>12%</td></tr><tr><td>Single Fault1</td><td>25%</td></tr><tr><td>Single Fault2</td><td>45%</td></tr></table></td><td>Not Publicly Available</td><td>Similar to predicate device
Meet the acceptance criteria as per ISO 17510 (<20% under normal condition and <60% under single fault condition).</td></tr>
<tr><td>AAV Inspiratory/Expiratory Resistance in Single Fault Condition</td><td>Inspiratory – 0.89 cm H2O
Expiratory – 0.63 cm H2O</td><td>Inspiratory – 0.6 cm H2O
Expiratory – 0.5 cm H2O</td><td>Not Publicly Available</td><td>Similar to predicate device
Meet the acceptance criteria as per ISO 17510 (<10</td></tr>
</table>

				cmH_2O).
Sound Pressure and Sound Power Level	Sound Pressure – 27.0 dBA Sound Power – 34.1 dBA	Sound Pressure – 29.98 dBA Sound Power – 32.99 dBA	Sound Pressure: 20.2 dBA, with uncertainty 2.5 dBA Sound Power: 28.2 dBA, with uncertainty 2.5 dBA	Similar to predicate device In accordance with ISO 17510, the values are detailed in the IFU.

Substantial Equivalence Discussion

Indications for Use

Both the subject devices and the predicate device are intended for use with Positive Airway Pressure (PAP) devices to provide airway pressure therapy for adult patients weighing over 30 kg. Both devices are available by prescription only and are intended for single-patient, multi-use in the home environment. The minor differences between them are strictly limited to language expression.

Therefore, the indications for use of the subject devices (JoyMask 20-B and JoyMask 21-B) are considered identical to those of the predicate device (Innova Full Face Vented Mask). No new risks regarding the indications for use are introduced.

Technical Characteristic and Performance

Both the subject devices and the predicate device are full-face masks designed to provide a seal over the user's face (covering both the nose and mouth) to deliver pressurized air from a positive airway pressure source.

In terms of technical characteristics, the subject devices are demonstrated to be similar to the predicate device and reference device. The minor technical differences have been fully evaluated in accordance with applicable standard and introduce no new risks. Therefore, the technical characteristics and performance of the subject devices (JoyMask 20-B and JoyMask 21-B) are substantially equivalent to those of the predicate device (Innova Full Face Vented Mask), raising no new questions of safety or effectiveness.

Performance Testing - Clinical

Not Applicable

Performance Testing - Animal

Not Applicable

Non-clinical testing

The following tests were conducted to verify the safety and effectiveness of subject devices.

Performance Testing

The following technical characteristic have been verified:

Dead Space, Exhaust Flow Characteristics, AAV Pressure, Resistance to Flow, CO2 Re-breathing Performance, AAV Inspiratory/Expiratory Resistance, Sound Pressure and Sound Power Level

Biocompatibility Testing

Biocompatibility testing was performed in accordance with the following standards:

ISO 10993-5 – Cytotoxicity

ISO 10993-10 – Sensitization

ISO 10993-23 – Intracutaneous Reactivity

ISO 18562-2 – Particulate Matter Release

ISO 18562-3 – VOCs Emissions with Toxicological Risk Assessment

ISO 18562-4 – Leachates in Condensates with Toxicological Risk Assessment

Other Testing

Transportation Testing

Cleaning Validation

Shelf Life and User Life Verification

Recognized Standards/Guidance

The subject devices comply with the following standards/guidance

Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff

Use of International Standard ISO 10993-1, Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process Guidance for Industry and Food and Drug Administration Staff

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

ISO 5356: Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets

ISO 17664: Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices

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 10993-10:2021 - Biological evaluation of medical devices - Part 10: Tests for skin sensitization

ISO 10993-17:2023 - Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents

ISO 10993-23:2021 - Biological evaluation of medical devices - Part 23: Tests for irritation

ISO 18562-1:2024 - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process

ISO 18562-2:2024 - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter

ISO 18562-3:2024 - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic substances

ISO 18562-4:2024 - Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate

Conclusion

Based on the information above, the subject devices (JoyMask 20-B and JoyMask 21-B) and the predicate device (Innova Full Face Vented Mask) have the same indication for use and similar technical characteristic.

The SE discussion and relevant data have demonstrated that the subjects devices are substantially equivalent to the predicate device and the differences do not raise new questions of safety and effectiveness.