December 31, 2024

Genadyne Biotechnologies, Inc.
Chien Ming Goh
Vice President
16 Midland Ave
Hicksville, New York 11801

Re: K243225
Trade/Device Name: Nasal Pillow Mask - Small (NNPM-01/ Nefes S); Nasal Pillow Mask - Medium (NNPM-02/ Nefes M); Nasal Pillow Mask - Large (NNPM-03/ Nefes L)
Regulation Number: 21 CFR 868.5905
Regulation Name: Non-continuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 17, 2024
Received: December 17, 2024

Dear Chien Ming Goh:

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, PhD
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)*
K243225

Device Name
Nasal Pillow Mask – Small (NNPM-01/ Nefes S);
Nasal Pillow Mask – Medium (NNPM-02/ Nefes M);
Nasal Pillow Mask – Large (NNPM-03/ Nefes L)

Indications for Use *(Describe)*
The Nasal Pillow Mask is intended for patients (> 30 kg) who have been prescribed CPAP/VPAP therapy in home, hospital, or institutional environments. This device is intended to be use under the direction of a physician.

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
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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."

510k Summary

Date Prepared

December 20, 2024

Company Name/Owner

Genadyne Biotechnologies, Inc.
16 Midland Ave,
Hicksville, NY 11801

Official Contact

Mr. Chien Ming (Andrew), GOH
chiengoh@genadyne.com
(t) 516.487.8787
(f) 516.977.8974

Device Name/ Trade Name

Nasal Pillow Mask – Small (NNPM-01/ Nefes S);
Nasal Pillow Mask – Medium (NNPM-02/ Nefes M);
Nasal Pillow Mask – Large (NNPM-03/ Nefes L)

Common/Usual Name

Patient interface for CPAP

Regulation Name and Product Code

21 CFR 868.5905 - Non-continuous ventilator (IPPB), BZD

Classification

Class II

Predicate Device

Hsiner Nasal Pillow Mask (K120920)

Device Description

The Nasal Pillow Mask is patient interface device intended for use with CPAP/VPAP therapy systems. The device provides non-invasive means of delivering positive airway pressure to the user by creating a sealed interface using nasal pillows that fit directly into the patients' nostrils. The Nasal Pillow Mask is made of silicone material and comes in 3 different sizes (S, M & L). The nasal mask comes with standard hose fitting intended to be used with standard CPAP/VPAP system. It is intended to be use on patients (> 30 kg) who have been prescribed CPAP/VPAP therapy at home, hospital, or institutional environments. The complete mask set incudes headgear, frame, tube, and nasal pillows (S, M, & L sizes).

Intended Use / Indications for Use

The Nasal Pillow Mask is intended for patients (> 30 kg) who have been prescribed CPAP/VPAP therapy in home, hospital, or institutional environments. This device is intended to be use under the direction of a physician.

Comparison to Predicate Device

The goal of this 510(k) is to re-introduce the predicate device under a different manufacturer and brand name as a result of an acquisition. The indications for use, design, principles of operation, and materials are all identical to the predicate device already cleared by FDA.

	Subject Device	**Predicate Device**
510(k) Number	K243225	K120920
Company	Genadyne Biotechnologies Inc.	HSINER Co. LTD.
Device Name	Nasal Pillow Mask	Hsiner Nasal Pillow Mask
Indications for Use	The Nasal Pillow Mask is intended for patients (> 30 kg) who have been prescribed CPAP/VPAP therapy in home, hospital, or institutional environments. This device is intended to be use under the direction of a physician.	The Hsiner Nasal Pillow Mask is intended to be use patients (> 30 kg) who have been prescribed CPAP/VPAP therapy in a home, hospital or institutional environments. This device is intended to be use under the specific direction of a physician.

<table>
<tr><td></td><td></td><td></td></tr>
<tr><td>Patient Population</td><td>Same</td><td>Adults</td></tr>
<tr><td>Use Environment</td><td>Same</td><td>Hospital, Home environment</td></tr>
<tr><td>Structure and Materials</td><td>Same</td><td>Nasal Plug: Silicone
Frame: Polycarbonate
L Connector: Polycarbonate
Tube: Hytrel®
Connector: Polycarbonate
Headgear: PC + Nylon Fabric</td></tr>
<tr><td>Specification</td><td>Same</td><td>
<table>
<tr><th>Items</th><th colspan="2">Specifications</th></tr>
<tr><td rowspan="3">Deadspace Volume</td><td colspan="2">S size: 90.8</td></tr>
<tr><td colspan="2">M size: 94.3</td></tr>
<tr><td colspan="2">L size: 95</td></tr>
<tr><td rowspan="4">Resistence</td><td>50 L/m</td><td>100 L/m</td></tr>
<tr><td>S size: 1.78</td><td>S size: 6.87</td></tr>
<tr><td>M size: 1.56</td><td>M size: 5.93</td></tr>
<tr><td>L size: 1.35</td><td>L size: 5.3</td></tr>
<tr><td>Therapy pressure</td><td colspan="2">5~20cmH_2O</td></tr>
<tr><td rowspan="4">Noise level</td><td colspan="2">10cmH_2O</td></tr>
<tr><td colspan="2">S size: 35.0~36.0</td></tr>
<tr><td colspan="2">M size: 34.2~35.6</td></tr>
<tr><td colspan="2">L size: 35.4~36.8</td></tr>
<tr><td>Environmental Conditions</td><td colspan="2">Storage and Transportation: 15°C ~ 25°C, up to 95% non-condensing
Storage relative humidity: <85%</td></tr>
<tr><td>Weight</td><td colspan="2">69.9g</td></tr>
</table>
<table>
<tr><th rowspan="2">Size</th><th colspan="4">Flow (l/min)</th></tr>
<tr><th>5 cmH_2O</th><th>10 cmH_2O</th><th>15 cmH_2O</th><th>20 cmH_2O</th></tr>
<tr><td>S</td><td>24.94</td><td>35.66</td><td>44.76</td><td>52.46</td></tr>
<tr><td>M</td><td>24.85</td><td>35.61</td><td>45.07</td><td>52.21</td></tr>
<tr><td>L</td><td>25.28</td><td>35.79</td><td>44.71</td><td>51.99</td></tr>
</table>
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Non-Clinical Performance Evaluation

The subject device is identical to predicate device except for manufacturer name, brand name, and resulting labeling updates. The indications for use, design, principles of operation, and materials are all identical to the predicate device already cleared by FDA. Therefore, no new non-clinical testing is required.

Conclusion

The subject device is identical to predicate device except for manufacturer name, brand name, and resulting labeling updates. The indications for use, design, principles of operation, and materials are all identical to the predicate device already cleared by FDA. Based on this comparison of intended use and technological characteristics of the subject device compared with the predicate device, we can conclude that the subject device is substantially equivalent to the predicate device.