

**K243225 Nasal Pillow Mask - Small (NNPM-01/ Nefes S)**Dec 31, 2024  
84 days to decisionK243225 · Product code: **BZD** · Anesthesiology  
Source: <https://www.510kdatabase.net/k243225/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ventilator, Non-continuous (respirator) (BZD)
Date received	Oct 8, 2024
Decision date	Dec 31, 2024
Days to decision	84 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Nasal Pillow Mask - Medium (NNPM-02/ Nefes M); Nasal Pillow Mask - Large (NNPM-03/ Nefes L)

**APPLICANT**

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Company	<b>Genadyne Biotechnologies, Inc.</b>
Location	Hicksville, NY, US
Contact	Chien Ming Goh
Website	<a href="https://www.genadyne.com">https://www.genadyne.com</a>
510(k) history	19 submissions · 19 cleared · 2008-2026

Genadyne Biotechnologies, Inc. specializes in advanced wound care solutions, particularly General & Plastic Surgery devices. Headquartered on Long Island, New York, the company manufactures and assembles products in the U.S. with a registered facility in Hicksville. Genadyne focuses on Negative Pressure Wound Therapy (NPWT) systems and advanced wound dressings, distributing globally across over 50 countries. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2008. General & Plastic Surgery devices represent 79% of its regula...