

K961915

AUG 15 1996



**RESPIRONICS INC.**

**Non-Confidential Summary of Safety and Effectiveness**

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May 13, 1996

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**Official Contact:** Francis X. Dobscha, Manager, Regulatory Affairs

**Proprietary or Trade Name:** Spectrum Reusable Full Face Mask

**Common/Usual Name:** Face Mask

**Classification Name:** Noncontinuous Ventilator (IPPB) Accessory

**Device:** Respiroics Spectrum Reusable Full Face Mask

**Predicate Devices:** Respiroics Spectrum Disposable Full Face Mask - K936047  
Vacumed Comfo-Seal Reusable Full Face Mask - K# unknown

**Device Description:**

The Spectrum Reusable Full Face Mask is an externally placed mask covering the nose and mouth (full face) of a patient. It is intended to provide a seal so that positive pressure from a positive pressure source is directed to the patient's nose and mouth. It connects to a patient circuit that contains an exhalation valve, tubing, and perhaps a humidifier and/or bacteria filter. It incorporates an Entrainment Valve which permits entrainment of ambient air when positive pressure to the patient ceases. The entrainment valve opens and closes based upon positive pressure being delivered to the patient. In addition, the mask incorporates a quick-release mechanism allowing the patient to quickly and easily remove the mask if desired. It is held in place with an adjustable headgear system. It is intended to be cleaned with soap and water. The cleaning process requires limited disassembly.

The Spectrum Reusable Full Face Mask may be used with an optional thin, pliable flap which may be used to improve the comfort and sealing of the basic unit. This accessory is referred to as the Comfort Flap. It is available either with the mask or sold separately as a replacement part.

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**Intended Use:**

Indicated Use -- Patient interface accessory for Respironics CPAP and BiPAP® Systems

Targeted Population -- Adult

Environment of Use -- Hospital and Home

**Comparison to Predicate Devices:**

Attribute	Respironics Reusable Spectrum Full Face Mask	Respironics Disposable Full Face Mask	Vacumed Comfo-Seal Reusable Full Face Mask
<b>Use</b>			
<u>Intended Use</u> -- Adult Obstructive Sleep Apnea (OSA)	Yes	Yes	Yes
Intended to be used with devices such as Respironics CPAP Systems and BiPAP Systems producing positive pressures $\geq 3.0$ cm H <sub>2</sub> O at the mask.	Yes	Yes	Yes
<u>Intended Environment</u> - Hospital: Adult OSA	Yes	Yes	Yes
<u>Intended Environment</u> - Home: Adult OSA	Yes	Yes	Yes

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**Comparison to Predicate Devices: (continued)**

Attribute	Respironics Reusable Spectrum Full Face Mask	Respironics Disposable Full Face Mask	Vacumed Comfo-Seal Reusable Full Face Mask
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<b>Design</b>			
Offered in various sizes	Yes	Yes	Yes
Intended for single patient multi-use	Yes	No	Yes
Made to be cleaned with soap and water	Yes	No	Yes
Provided non-sterile	Yes	Yes	Yes
Incorporates an Entrainment Valve	Yes	Yes	No
Adapts to headgear	Yes	Yes	Yes
<b>Performance Standards/Specifications</b>			
Entrainment valve activation pressure of 3.0 cm H <sub>2</sub> O minimum	Yes	Yes	Not Available
Meets design requirements after cleaning	Yes	Yes	Yes

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**Performance Features:**

Qualification tests were performed with samples of the intended device covering the following basic areas:

- Initial performance characteristics of the device and components
- Environmental performance simulating shipping, storage and usage, including cleaning
- Performance after environmental simulations of the device and components
- Performance at extreme user conditions
- Performance of repeated disassembly / reassembly of the Entrainment Valve

Test results show that the Spectrum Reusable Full Face Mask meets all functional and key requirements as defined in the product design specifications.