K960518

SECTION 16. 510(k) SUMMARY

MAY - 9 1996

(1) Company Information

Owner/Operator:	Puritan-Bennett Corporation Registration Number 9919005
Manufacturing Site:	Puritan-Bennet Corporation 9728 Pflumm Road Lenexa, KS 66215 Registration Number 1933149
Official Correspondent:	C. Marshall Smith Phone: 913-495-4845 Direct Dial 913-495-4845 Fax: 913-394-8764
Date of Summary Preparation:	2 February 1996

(2) Device Name:

Proprietary Name:	Puritan-Bennett 318 Plus Nasal CPAP System
Common Name:	CPAP Machine
Classification Name:	Noncontinuous Ventilator, per 21 CFR 868.5905 and 73 BZD

(3) Equivalent Devices:

Primary Predicate Device:	Puritan-Bennett C314 Nasal CPAP System, K952292
Other Predicate Devices:	Puritan-Bennett C318 Nasal CPAP System, K903764
	Puritan-Bennett 335 Respiratory Support System, K942210 (pending)
	Healthdyne Tranquility Quest Compact Nasal CPAP System Model 7300, K943509

(4) Device Description:

The 318 Plus Nasal CPAP System is a device used to provide Continuous Positive Airway Pressure between 3 and 18 cm H2O.

The device is a modification to the Puritan-Bennett C314 Nasal CPAP System, which adds some additional features.

The device is powered by AC Mains from 100 to 240 VAC, 50/60 Hz by utilizing a standard automatic switching power supply similar to the one in the PB335 Respiratory Support System.

The device is set up for use by the homecare provider using the Set-up Instructions provided with the device. It is operated using the Patient Guide.

The pressure is set to the prescription with the use of a patient circuit, with the pressure being measured at the patient end of the circuit. By using this method, losses associated with the patient circuit are compensated for and thus the device does not require a pressure transducer. The motor maintains a constant speed through the feedback loop from the motor to the motor drive circuit.

The device has a ramp function. This allows the patient to reduce the pressure when first going to bed to make it more comfortable to fall asleep. The available ramp times are 0, 5, 10 or 20 minutes. The ramp duration is set up by the homecare provider by use of the Ramp Duration Switches. The ramp starting pressure can be adjusted by the patient using the Ramp Starting Pressure Adjustment switches. The ramp feature can be activated and deactivated by pressing the Ramp Button.

Both the prescription pressure and the ramp pressure can be seen in the Pressure Display on the top housing.

The optional Compliance Meter measures patient compliance by measuring changes in the motor current as the patient breathes on the device.

The accessories, i.e., the patient tubing, patient masks and headgear are the same ones used with the C314 and PB335.

The device is not for life-supporting or life-sustaining situations.

The device is for prescription use.

The device itself, the air filter and the humidifier are for multiple use. The other accessories, i.e., the patient tube, nasal masks and headgear are for single patient use.

The device is not software-driven.

Neither the device nor its accessories are sterile.

(5) Intended Use:

The intended use of the 318 Plus Nasal CPAP System is to provide Continuous Positive Airway Pressure (CPAP) between 3 and 18 cm H2O to spontaneously breathing adult patients for the treatment of Obstructive Sleep Apnea in a homecare environment. This is the same intended use as for the C314 Nasal CPAP System.

(6) Technological Characteristics:

The device has the same technological characteristics as the primary predicate device, inasmuch as the two devices use either the same or similar components and the two devices function in the same manner.

(7) Nonclinical Tests Submitted:

The device was tested in accordance with the "Electrical Performance Testing" and "Mechanical and Environmental Testing" sections of Appendix A of the "Draft - Reviewer Guidance for Premarket Notifications, Anesthesiology and Respiratory Branch" document dated November 1993. The device passed all of the tests.

Static and dynamic pressure testing was also performed. The results of the testing demonstrated that the 318 Plus performed in the same manner as the primary predicate device, the C314.

The device was also tested when powered by a 12 volt DC power supply using the optional DC to AC inverter. The results of the testing demonstrated that the device's performance was the same as when powered by AC Mains.

(8) Clinical Tests Submitted:

None.

(9) Conclusions from Tests:

As stated in Section (7) above, all of the testing demonstrated that the 318 Plus is as safe and effective and performs as well or better than the primary predicate device, the C314.