8/15/94 K936000

SUMMARY OF SAFETY AND EFFECTIVENESS
PER SAFE MEDICAL DEVICE ACT OF 1990

SUBMITTER: Puritan-Bennett Corporation
Ventilator Systems Division
2200 Faraday Avenue
Carlsbad, CA 92008

DATE: December 10, 1993

DEVICE NAME: Respiratory Gas Humidifier

PROPRIETARY NAME: Cascade I Series Humidifier (modified device)

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CLASSIFICATION: Class II, per 21 CFR 868.5450

PREDICATE DEVICE: Cascade I Series Humidifier

1. DEVICE DESCRIPTION:

The 510(K) premarket notification pertains to a modification to the predicate device, the Puritan-Bennett Cascade I Series Humidifier. The modification consists of two types of product changes: 1) physical improvements, and 2) improvements to the labeling. These changes are proposed in order to improve device safety in the event of an electrical module malfunction or user misuse. The modified device is considered to be substantially equivalent to the unmodified device.

The redesign of the bubbler, including the new bubbler and stud polysulfone material and added spacing between the bubbler and heater, provides added safety from overheating. The new thermal well attachment helps to prevent incorrect use of the humidifier; operating without the thermal well in place. The new baseplate polysulfone material also provides added safety from overheating and the new housing and bracket Noryl material is not significantly different from the original grade.

2. INTENDED USE:

Both the modified and the predicate Cascade I Series Humidifiers are intended for use as respiratory gas humidifiers and for use with continuous ventilator devices. The Cascade I Series Humidifier contains a water collecting vessel and heats and humidifies the air in the inspiratory ventilatory circuit.

3. COMPARISON OF LABELING:

The modification of the device Operational Check procedure provides more specific instructions, increases the recommended frequency the operational checks procedure is completed, and provides an alternative thermoswitch test, all of which contribute to added device safety. The Operator's Manual is revised in accordance with all device physical and labeling changes. The addition of the Cascade Ia Semiannual Performance Verification Instructions increases the instructed performance frequency of the electrical module tests, thereby providing added assurance of the device safety. The new Cascade I Series Bubbler Upgrade Kit with installation instructions allows for modification of devices in the field to the new, safer design. Existing warnings remain in Operator's Manual and the addition of Fire Hazard Warning Labels to the humidifier provides added emphasis to the warnings concerning the requirements for the thermal well to be in place and for sufficient water during device operation.

4. SUBSTANTIAL EQUIVALENCE:

The modified Cascade I Series Humidifier is considered to be substantially equivalent to the existing device. The physical and labeling product modifications comprise a significant improvement to device safety.

The product's intended use is unchanged by the modifications. Technological characteristics, as described above, are altered to improve product safety. These new technological characteristics do not raise new types of safety of effectiveness questions. Physical and functional performance tests, validation activities, and safety and hazard analyses have been conducted and demonstrate the product modifications to be safe and effective. Therefore, information provided in the 510(k) submission supports the determination of substantial equivalence.