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510(k) SUMMARY

Per the Safe Medical Devices Act of 1990, the following summary of Puritan-Bennett Corporation's Proportional Solenoid Valve (PB-PSOL) premarket notification is provided for public dissemination.

The purpose of pneumatic assemblies within ventilators is to deliver medical gases to patients in the proper volume, flow rate, pressure, and mixture. These assemblies are composed of tubing, filters, flow transducers, pressure transducers, regulators, check valves, pressure switches, and proportional solenoid valves. For ease of presentation, the two proportional solenoid valves which are mounted to a common base will be referred to as one assembly (i.e., PSOL). The role of a PSOL is to proportionally open or close its two internal valves to govern flow of air and oxygen. The position of each valve is controlled by the ventilator's microprocessor and electronics circuitry. Feedback to the microprocessor from flow and pressure transducers allows immediate fine adjustment to PSOL function. By this method, the microprocessor controls the characteristics of breath delivery based upon the clinician's settings for ventilatory therapy.

The PB-PSOL operates in the following manner. When current is applied to a copper wire coil, an induced (magnetic) field acts upon an armature assembly which pulls a poppet away from its seat. The nonmagnetic poppet and seat serve as barriers to gas flow within the PB-PSOL. The greater the applied current the farther the poppet will move; resulting in higher gas flow. The "flow-versus-current" curve of a PB-PSOL displays an approximately linear function over the design range.

Puritan-Bennett has used PSOLs in 7200 Series ventilators since May, 1983. This series includes models 7200 (K823858B; cleared 5/83), 7200a (K843424/A; cleared 11/84), and 7200ae (K902506B; cleared 1/90). To date, Puritan-Bennett Corporation has sold approximately twenty thousand (20,000) 7200 Series ventilators for domestic and international clinical applications.

The predicate PSOL is P/N 20800. The principle distinction between P/N 20800 and the PB-PSOL is in the geometry of the armatures which move the poppets. The former uses an additional magnet to achieve relative linearity for the flow-versus-current curve. The armature geometry of the latter does not require such a magnet. Either PSOL can be installed directly into a 7200ae ventilator without software or hardware modifications.

The hazard analysis for the Model 7200ae ventilator was reviewed to identify any risks associated with PSOL functions. Upon review of a Failure Mode and Effects Analysis for the PB-PSOL and the content of the above document, it was determined that use of the PB-PSOL would not raise new types of safety or effectiveness issues nor alter the likelihood of occurrence of theoretical risks. Therefore, the hazard analysis is identical for ventilators using the PB-PSOL or P/N 20800 (K902506B).

To ensure that the PB-PSOL met all its functional requirements and that 7200ae ventilators utilizing PB-PSOLs operated per design intent, two levels of testing were performed. Component-level tests evaluated whether isolated valves performed within design specifications. System-level tests assessed interaction of the PB-PSOL with other ventilator components to assure that the software-controlled microprocessor circuitry provided breath delivery within system specifications.

Fifteen PB-PSOLs were evaluated against each requirement of the Proportional Valve Specification. The acceptance criteria for all component-level tests were met. Ten of the fifteen valves were subjected to, and passed, the "life" test. These fifteen PB-PSOLs were then placed into fifteen 7200ae ventilators to conduct system-level evaluations. A total of one-hundred-thirty (130) individual ventilator performance characteristics were assessed by a test stand called the System Performance and Service Tester (SPST). Seven test sections were specific to PSOL function. The remaining tests assessed other components or the ventilator's output while under control of its microprocessor. This assured that the PB-PSOL did not negatively affect other assemblies in an unanticipated manner. The test results demonstrated that the seven system-level evaluations specific to the PSOL were successfully completed. Furthermore, all other system-level tests performed by the SPST provided evidence of ventilator performance per specification. It was concluded that the PB-PSOL is functionally equivalent to the predicate valve.

In conclusion, Model 7200ae Ventilators incorporating either PSOL have the same indications for use, modes of therapy, technological characteristics, and performance specifications. Puritan-Bennett Corporation concludes that the PB-PSOL is substantially equivalent to P/N 20800.