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DeVilbiss Health Care, Inc.
1200 East Main Street
P.O. Box 635
Somerset, PA 15501-0635
U.S.A.
(814) 443-4881
Fax: (814) 443-7572

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16.0 510 (k) Summary
Summary of Safety and Effectiveness

Firms name: DeVilbiss Health Care, Inc.
Pulsair Division
P.O. Box 2609
4106 Avenue D
Fort Pierce, Fla. 34954
Submitter's name: Gregory W. Good
Phone: (814) 443-7466
Fax: (814) 443-7571
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Trade name: Oxygen Management Systems
Common name: Pulse Dose Series
Classification name: Non-Continuous Ventilators 73BZD (21 CFR 868.5905)

The Pulse Dose Series devices are fundamentally repackaged versions of the OMS 20 and 50, DeVilbiss' current Oxygen Management Systems. The devices provide a bolus of oxygen to a patient at the start of inhalation. The devices assist patients, who require prescribed doses of supplemental gases such as oxygen, to conserve gas from the various gaseous cylinders or liquid oxygen reservoirs. By allowing oxygen to flow only from the cylinder or liquid oxygen reservoirs during the inspiratory segment of a patient's breathing cycle, conservation occurs.

The gas dosage methodology, oxygen delivery specifications, and performance of the devices in the Pulse Dose Series are identical to those of the OMS 20 and 50. This is evidenced in the various comparison matrices and testing reports contained in this 510(k). This equivalency is also evidenced in the non-clinical testing which reveals the same dosage delivery when comparing the predicate devices with the devices in the Pulse Dose Series. The device's performance to the end user are identical as compared to the OMS 20 and 50.

When compared to the predicate devices, the OMS 20 and 50, the devices in the Pulse Dose Series utilize the same type of energy source, and there are no significant changes in the materials or features.

All the devices in the Pulse Dose series utilize batteries as the energy source, as do the OMS 20 and 50. The fundamental operational features are identical; however, the devices in the Pulse Dose Series include some additional features, e.g.,battery level indicator, which make the devices more user friendly.

The differences between the devices in the Pulse Dose Series and the OMS 20 and 50 can be categorized as additional patient features (battery level indicator), technological improvements (microprocessor control), or re-packaging (improved cosmetics and manufacturing /servicing assembly). Tests and analysis indicate that there is no greater risk to the end user than there is with the predicate devices. These device improvements were intended to make the devices in the Pulse Dose Series more user friendly while increasing their reliability, without altering their performance for the end user.

Therefore, based on the above mentioned similarities, especially the dosage methodology, the Pulse Dose Series devices and the OMS 20 and 50 are substantially equivalent devices.