

**OHMEDA**

THE BOC GROUP

K946127

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**Subject:** 510(k) Summary of Safety and Effectiveness Information for the Ohmeda Excel Draw-Over Military Vaporizer System

**Proprietary:** Ohmeda Excel Draw-Over Military Vaporizer System

**Common:** Anesthesia Machine

**Classification:** Primary: Gas Machine for Anesthesia Class II 21CFR868.5160 - 73BSZ  
 Secondary: Anesthetic Vaporizer (non heated) Class II 21CFR868.5880 - 73CAD  
 Breathing Gas Mixer Class II 21CFR868.5330 - 73BZR  
 Uncompensated Thorpe Tube Flowmeter Class II 21CFR868.2320 - 73CCN

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMMA 1990 and 1992.

The Ohmeda Excel Draw-Over Military Vaporizer System is substantially equivalent to the following currently marketed Ohmeda devices:

1. Ohmeda 'B' Series Gas Delivery System (currently known as the Ohmeda Excel Anesthesia System) which was the subject of a cleared 510(k) premarket notification on 10/30/86 with FDA log number K863207.
2. Ohmeda PAC Portable Anesthesia Machine that was the subject of a cleared 510(k) premarket notification on 7/1/85 with FDA log number K850848A.
3. Ohmeda Universal PAC Portable Anesthesia Machine that was the subject of a cleared 510(k) premarket notification on 9/7/90 with FDA log number K901117A.

The Ohmeda Excel Draw-Over Military Vaporizer System is specifically designed for use with the Ohmeda Single-Agent Draw-Over Vaporizer. It consists of an Excel 210 system with an attached draw-over vaporizer. The purpose is to provide a platform for the delivery of inhalation anesthetic agents using the draw-over vaporizer and supplemental gas supply.

The Ohmeda Excel Draw-Over Military Vaporizer System is a modification of the Ohmeda Excel 210 that has been made to facilitate the Ohmeda Single-Agent Draw-Over Vaporizer and the military needs. The system consists of an Ohmeda Single Agent Draw Over Vaporizer and a kit that allows the vaporizer to be used with an Ohmeda Excel system. The kit consists of mounting attachments, O2 flush cover, monitoring ports, scavenging interconnection, and an extended length oxygen enrichment tube.

The Ohmeda Excel Draw-Over Military Vaporizer System was designed to comply with the applicable portions of the following voluntary standards;

1. ASTM F1161-1988 - "Standard Specification for Minimum Performance and Safety Requirements for Components and Systems of Continuous Flow Anesthesia Machines".
2. MIL-STD-1472B - "Human Engineering Design Criteria for Military Systems, Equipment and Facilities".

Standards agencies, such as U.L. and E.T.L., do not provide specific certification services for this type of device.

The Ohmeda Excel Draw-Over Military Vaporizer System and the currently marketed devices are substantially equivalent in technological characteristics, theory of operation, and use of accessories.