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K963994

**Summary of Safety and Effectiveness Data Relating to Substantial Equivalence**

Proprietary Name: Narkomed GS Anesthesia System

Classification Name: Gas-Machine, Anesthesia 73BSZ

Device Class: Class II

Manufacturer: North American Dräger  
3135 Quarry Road  
Telford, Pennsylvania 18969

Establishment Registration Number: 2517967

Devices to which substantial equivalence is claimed:

Narkomed 2C Anesthesia System K930351/A

Narkomed AV2+ Anesthesia Ventilator K953228

**Device Description:**

The NMGS is a continuous flow gas anesthesia system.

**Intended Use:**

The NMGS may be used for spontaneous, manually assisted, or automatic ventilation, and delivery of gases and anesthetic vapor. The NMGS can monitor oxygen concentration, breathing pressure, and respiratory volume.

**Substantial Equivalence:**

The NMGS is substantially equivalent to the Narkomed 2C (NM2C) and the AV2+ Anesthesia Ventilator (AV2+).

The NMGS, like the NM2C is an anesthesia system with integrated monitors for oxygen concentration, breathing pressure and respiratory volume. The gas delivery system, absorber and scavenger of the NMGS are the same design that is used on the NM2C. The NMGS uses the AV2+ anesthesia ventilator. The AV2+ is marketed as an integral subassembly of North American Dräger anesthesia systems, including the NM2C.

The NMGS like the NM2C is available with a serial interface for communication via the Vitalink serial link protocol to devices such as NAD's Vitalert 2000 and 3000 monitors.

The NMGS differs from the NM2C by offering an optional two vaporizer configuration of the system as well as the three vaporizer configuration.

The NMGS and the NM2C have the same intended use and principal of operation and are substantially equivalent.

Qualification of the NMGS included hazard analysis, software verification, and qualification testing, environmental testing, and electromagnetic compatibility testing.