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K961742

## Summary of Safety and Effectiveness

### INTENDED USE

The Drager DVE 8080 System is a piece of durable equipment intended to provide ceiling mounted overhead physical support for anaesthesia machines, medical/surgical monitoring and related equipment, storage space, and ceiling mounted dispensing of medical gases and electrical power required in clinical settings, emergency rooms, intensive care, procedure rooms and operating rooms.

The DVE 8080 will be used in the same indications as the DVE 4000 System and the DVE 8000/1/2 System and the Drager 8032E which provide physical support, storage space, and overhead, ceiling mounted dispensing of medical gases and electrical power. The DVE 4000 has previously been reviewed by FDA (K921297). The Drager 8000/1/2 Series System and the combined DVE 8000/1/2 with DVE 4002 have been previously reviewed by FDA (K942043). The new DVE 8080 Series will be used in indications which are the same as indications for the DVE 4000, DVE 8000, DVE 8032E and for other pendant systems currently offered for commercial distribution in the United States.

### PRODUCT DESCRIPTION

ALM Surgical Equipment Inc. will be the distributor of the Drager DVE 8080 Series in the United States. The DVE 8080 System is manufactured by Dragerwerk, Aktiengesellschaft Lubeck, Federal Republic of Germany.

The DVE 8080 Series System is a ceiling mounted overhead supply system of modular design. The individual components of any modular system are divided into four categories: ceiling fixture, support systems, pendant head or column, and equipment carrier.

The pendant column contains four terminal plates that can be outfitted according to the individual need with various outlets for gas supply, electricity, vacuum, communications, etc.

Add-on terminal boxes are available which allow the user the opportunity to meet individual equipment needs most efficiently. Add-on terminal boxes can be installed at the time of purchase or anytime afterwards.

The support system consists of either a fixed vertical support tube (DVE 8080 basic version of the series) or a single (DVE 8081) support arm or two (DVE 8082) support arms. The support arms are equipped with pneumatic brakes and are available in three combinable lengths.

The DVE 8080 Series System rotates laterally and is powered for up and down adjustment. The motor used in the DVE 8080 is an induction motor manufactured by Gefeg GmbH & Co KG. The differences between the DVE 8032E Series motor and the DVE 8080 Series motor are:

	DVE 8080	DVE 8032E
Rated voltage:	190V/60Hz	110V/60Hz
Rated Input:	1.37A	1.7A
Speed:	3300 1/min	103 1/min
P1:	336W	255W
Capacity:	-	30u/400V
	three-phase current	alternating current

The equipment shelf provides for better positioning of the medical devices required and can be installed at time of purchase or added-on afterwards. Shelves are available in one standard size: 620 mm (width) by 400 mm.

The Drager DVE 8080/81/82 Systems have been tested and registered with Underwriters Laboratories (UL). All parts are in accordance with the National Electrical Code, ANSI/NFPA.

Maximum load-bearing capacities have been established for possible numbers and lengths of carrying arm combinations. These numbers have been derived from both UL testing and in-house testing.

The Drager DVE 8080 Series Systems can be used alone or in combination with the DVE 4000/1/2 Series System.

#### RATIONALE FOR SUBSTANTIAL EQUIVALENCE

The Drager DVE 8080 Series System is substantially equivalent in materials, design, and function to pre-enactment devices of similar intended use, as well as to other pendant anaesthesia supply and monitoring support systems currently in commercial distribution in the United States.

The Drager DVE 8080 Series is substantially equivalent to:

- 1) The DVE 8031/2 Series (K921297) and,
- 2) The DVE 8032E Series (powered for vertical adjustment) (K942043)
- 3) The AMSCO Ceiling Mounted Surgical ORBITER System,
- 4) The Heraeus Hanauport 810 Universal Ceiling Column

All of these systems are ceiling mounted pendant systems intended to provide overhead support for anaesthesia machines, medical/surgical monitoring and related equipment and to provide physical support for ceiling mounted dispensing equipment of medical gases and electrical power.

All of these systems are modular in design to allow for maximum flexibility in meeting the needs of individual users and sites.

The main differences between the DVE 8080 Series System and the DVE 8032E Series System are:

- 1) The position of the motor is changed. The 8032E motor is between the end of the first arm and the beginning of the second arm. The 8080 system motor is located directly above the pendant column.
- 2) The weight load capacity of the DVE 8080 Series (250 kg) is larger than the weight load capacity of the 8032E (70 kg).

The following charts provide a comparison of features of the DVE 8080 system to two other similar commercially marketed systems.

Table I compares the features of the DVE 8080 Series System to the comparable motorized, vertically adjustable DVE 8032E System.

Table II compares the features of the DVE 8080 Series System to the comparable motorized, vertically adjustable ORBITER system offered for commercial distribution by AMSCO in the United States.

TABLE I

	DVE 8080	DVE 8032E
Marketed By	ALM Surgical	ALM Surgical
Intended Use	Support for Medical Equipment, Storage, Electrical and Gas Support for Equipment	Support for Medical Equipment, Storage, Electrical and Gas Support for Equipment
Components	Factory Installed Add-ons (prefabrication)	Factory Installed Add-ons (prefabrication)
	Vertical Support Tube 2 Arms (single or double) Pendant Column Ceiling Fixture	Vertical Support Tube 2 Arms (single or double) Pendant Column Ceiling Fixture
Features and Technical Specifications	48 pre-installed medical gas outlets and/or electrical receptacles in any combinations and of any manufacturer.	24 pre-installed medical gas outlets and/or electrical receptacles in any combinations and of any manufacturer.
	Quick connect or D.I.S.S. outlets. Hospital grade electrical receptacles.	Quick connect or D.I.S.S. outlets. Hospital grade electrical receptacles.
	Fully Rotational, Fully Articulated Or Fixed Height	Fully Rotational, Fully Articulated Or Fixed Height
	Pendant Column	Pendant Column
	3 Combinable Lengths For Support Arms	3 Combinable Lengths For Support Arms
Motor	190 v, 60 Hz	110 v, 60 Hz
Compatible Inserts	Any Manufacturer, Including Chemetron, Puritan Bennett, Ohio Med. Prod., Oxyquip.	Any Manufacturer, Including Chemetron, Puritan Bennett, Ohio Med. Prod., Oxyquip.
Allowed Vertical Movement	23.6 inches	23.6 inches

Table II

	DVE 8080	ORBITER
Marketed By	ALM Surgical	AMSCO
Intended Use	Structural Support for Medical, Electrical and Gas Equipment. Conduit for Wires, Hose.	Support for Medical Equipment, Storage, Electrical and Gas Support for Equipment
Components	Factory Installed Add-ons or Site Installed	Factory Installed Add-ons (prefabrication)
	Vertical Support Tube 2 Arms (single or double) Pendant Column Ceiling Fixture	Vertical Support Tube Arm (single or double) Pendant Column Ceiling Fixture
Features and Technical Specifications	48 pre-installed medical gas outlets and/or electrical receptacles in any combinations and of any manufacturer.  Quick connect or D.I.S.S. outlets. Hospital grade electrical receptacles.  Fully Rotational, Fully Articulated Height Adjustable  Pendant Column or Head  3 Combinable Lengths For Support Arms	12 pre-installed medical gas outlets and/or electrical receptacles in any combinations and of any manufacturer.  Quick connect or D.I.S.S. outlets. Hospital grade electrical receptacles.  Fully Rotational, Fully Articulated Height Adjustable  Variable Lengths, 24 to 34 inches 3 Combinable Lengths  Premarket Notification K831086
Compatible Inserts	Any Manufacturer, Including Chemetron, Puritan Bennett, Ohio Med. Prod., Oxyquip.	Any Manufacturer, Including Chemetron, Puritan Bennett, Ohio Med. Prod., Oxyquip.
Motor	190 v, 60 Hz	
Allowed Vertical Movement	23.6 inches	28 inches