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K961386

Summary of Safety and Effectiveness
Gemina Wall-Mounted Workplace System

INTENDED USE

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

The Gemina System will be used in the same indications as other systems which provide overhead or wall mounted physical support and storage of equipment for dispensing of medical gases and electrical power. Another Drager System, the DVE 4000, a ceiling mounted system has previously been reviewed by FDA (K921297).

PRODUCT DESCRIPTION

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

The Gemina System is a wall mounted supply system of modular design. The individual components of this modular system are wall fixture, horizontal element, column, support tube, and equipment carrier (shelf).

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

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

The Drager Gemina System is substantially equivalent to another Drager system, the DVE 4000, a ceiling mounted system which has previously been reviewed by FDA (K921297).

The Drager Gemina System is also substantially equivalent to the Horizon Headwall System from Hill-Rom.

Both of these systems (Gemina and Horizon) are wall mounted systems intended to provide support for medical/surgical monitoring and related equipment and to provide physical support for wall mounted dispensing equipment of medical gases and electrical power.

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

The following charts provide a comparison of features of the Gemina System to The Horizon Headwall System:

TABLE I

	Gemina	Horizon Headwall
Marketed By	ALM Surgical	Hill-Rom
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)
Features and Technical Specifications	Quick connect or D.I.S.S. outlets. Hospital grade electrical receptacles.	Quick connect or D.I.S.S. outlets. Hospital grade electrical receptacles.
	Wall Mounted	Wall Mounted
Compatible Inserts	Any Manufacturer, Including Chemetron, Puritan Bennett, Ohio Med. Prod., Oxyquip.	Any Manufacturer, Including Chemetron, Puritan Bennett, Ohio Med. Prod., Oxyquip.

Safety Features

All of the Drager systems described in this premarket notification are equipped with the following safety features:

- Metal edges are covered with plastic band to protect all cables and hoses that could be enclosed from possible cutting by those edges.
- All edges are rounded. A sturdy plastic guide is provided to guide hoses and cables to connections.

ADVERSE SAFETY AND EFFECTIVENESS INFORMATION

For correct and effective use of the Gemina System and to avoid potential safety hazards, it is essential to follow the recommendations contained in the manual provided with the device. Any use of the apparatus requires full understanding and strict observations of these instructions. The apparatus is only to be used for purposes specified here.

The apparatus must be inspected and serviced by experts at regular 6 month intervals. Care must be taken to observe the recommended maximum loads recommended in the product literature. Failure to observe the recommended maximum loads could result in injury or harm to patients and healthcare professionals.

Professional installation is required to ensure that all standards and codes for gas and power connection as well as mechanical connections are met. Failure to meet these standards could result in injury or harm to patients and healthcare personnel.