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510(k) SUMMARY - ODS1 HOOD DRIVER

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DEVICE INFORMATION:

Trade name: ODS1 - Hood Driver
Common name: Hyperbaric Chamber Breathing Station
Classification name: Chambers, Hyperbaric 73CBF

DESCRIPTION:

The Model ODS1 - Hood Driver is intended for use with monoplace hyperbaric chambers. It is normally used to permit the patient to breath oxygen while the chamber is pressurized on air. However, it can be used to supply the patient with any physiologically appropriate gas which may or may not be the same as the gas used to pressurize the chamber.

The ODS1 circuit is designed to supply a steady flow of breathing gas to the breathing apparatus used in the chamber. The breathing apparatus can be either a "Sea-Long" hood or a free-flow mask arrangement.

INDICATIONS:

Hyperbaric chambers are used for treating the indications as currently listed by the Undersea Hyperbaric & Medical Association for hyperbaric oxygen therapy.

COMPARISON TO EXISTING EQUIPMENT:

Similarities:

The ODS1 is substantially equivalent to the breathing stations found in larger hyperbaric chamber systems, such as the Lifeforce Hyperbaric Chamber System (K951125) built by Reimers Engineering. They are similar in the following ways:

1. Supplies a steady flow of breathing gas to the breathing apparatus.
2. Controls a steady exhaust flow from the breathing apparatus to the chamber exterior.

3. Can be used with both hoods and constant flow masks.
4. Designed around standard 22 mm respiratory fittings.
5. Patient is adequately protected from suction injury caused by excessive exhaust flow or inadequate supply flow.
6. Requires minimal flow adjustments after initial setup.
7. Same range of supply flow control: ODS1: 20 - 200 scfh
Lifeforce: 21 - 212 scfh
8. Works with oxygen or air.
9. Same wetted materials (Copper, Brass, Stainless-Steel)
10. 100% oxygen compatible softgoods

Differences

The significant differences between the ODS1 - Hood Driver and the Lifeforce breathing stations are as follows:

1. The Lifeforce breathing stations are located inside the chamber. The ODS1 controls can be placed inside or outside of the chamber. With the controls outside of the chamber, an outside attendant sets the controls instead of an inside attendant.
2. The Lifeforce breathing stations contain an additional supply flowmeter and throttle valve for a separate nebulizer flow. The ODS1 has only one supply flowmeter and throttle valve. The ODS1 can still be used with certain types of nebulizers if desired. However the additional dedicated nebulizer circuit has been found unnecessary for most monoplace chamber applications.

DISCUSSION:

Neither of these differences affect the safety or effectiveness of the ODS1 which is inherent in the circuit design. The differences are only related to the packaging of the circuit.

CONCLUSION:

The ODS1 - Hood Driver is substantially equivalent to existing, legally marketed devices.