

K961530

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY NAME AND CONTACT PERSON

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DEC - 5 1996

Jack W. Brown
President

DEVICE NAME

MODEL NUMBER

Gish Reliance™ Oxygenator

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NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

COBE *Optima* Oxygenator (K923272) and Sorin *MONOLYTH* Oxygenator (K922933).

DESCRIPTION OF DEVICE

The Gish Reliance™ Oxygenator is designed to control blood gases in the extracorporeal circuit during cardiopulmonary bypass surgery.

The Gish Reliance™ Oxygenator is a sterile, non-pyrogenic, single use, disposable extracorporeal device. It is intended for the supply of oxygen to, and the removal of carbon dioxide from, the blood of humans. An integral heat exchanger is included which is intended to control the temperature of the blood. The Gish Reliance™ Oxygenator has one (1) blood inlet located at the bottom of the assembly, an integral heat exchanger intended to control the temperature of blood, a bundle of microporous hollow fibers for the exchange of gases, two (2) blood outlet ports, one (1) gas inlet port, one (1) gas outlet port and three (3) gas vents to prevent over pressurization.

The design of the oxygenator allows for a bottom-up flow of blood through the heat exchanger and around and between the hollow fibers of the gas exchange bundle. The bottom-up flow aids in priming and air removal from the unit. Once the blood reaches the top of the unit, it flows into a manifold which directs the blood downward and out the main blood outlet. The other blood outlet port is located at the top of the unit and may be used for air removal or recirculation.

Gas enters the oxygenator through a gas inlet located at the top of the unit and then flows downward (countercurrent to the blood flow) through the inside of the hollow fibers. Gas exchange occurs with the blood through diffusion across the hollow fiber membrane. Gas leaves the oxygenator through gas outlets or vents. One (1) gas outlet port is provided to scavenge gas leaving the oxygenator.

The integral heat exchanger controls the temperature of blood. Blood flows on the outside of the heat exchanger while heated or cooled water flows on the inside. Heat is transferred between the blood and water by the stainless steel bellows.

STATEMENT OF INTENDED USE

The Gish Reliance™ Oxygenator is indicated for use in procedures requiring the extracorporeal oxygenation of, and carbon dioxide removal from, human blood. It is designed to operate at blood flow rates of one half (0.5) to eight (8.0) liters per minute for periods of up to six (6.0) hours.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The COBE *Optima* Open System is intended to be used in adult surgical procedures requiring extracorporeal gas exchange support and blood temperature control for periods of up to six hours.

The Sorin *MONOLYTH* has been designed to substitute lung function in an extracorporeal bypass circuit by providing oxygenation and removal of carbon dioxide from venous blood. The *MONOLYTH* integrates a high efficiency heat exchanger and a hardshell venous reservoir. The *MONOLYTH* is indicated for use with blood flows of 1 to 8 liters per minute ("LPM"). The *MONOLYTH* has been tested for 6 hours of continuous use. Use of this device for more than 6 hours is not advised.

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

The Gish Reliance™ Oxygenator has technological characteristics which are substantially equivalent to the COBE *Optima* Oxygenators (K923272) and the Sorin *MONOLYTH* Oxygenators (K922933). The design, construction, materials and nominal specifications of the Gish Reliance™ Oxygenator are either identical or substantially equivalent to COBE *Optima* Oxygenators or Sorin *MONOLYTH* Oxygenators.

A Device Comparison Chart comparing the technological characteristics of the Gish Reliance™ Oxygenator with two substantially equivalent devices, the COBE *Optima* Oxygenators and the Sorin *MONOLYTH* Oxygenators is provided in Appendix III.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This premarket notification submission provides substantial equivalence information and rationale which addresses the introduction to commercial distribution of the Gish Reliance™ Oxygenator. The Gish Reliance™ Oxygenator is substantially equivalent to other oxygenators which are in commercial distribution. These predicate/marketed devices include the COBE *Optima* Oxygenators (K923272) and the Sorin *MONOLYTH* Oxygenators (K922933).

The Gish Reliance™ Oxygenator has an intended use which is substantially equivalent to other oxygenators which are in commercial distribution, such as the COBE *Optima* Oxygenators or Sorin *MONOLYTH* Oxygenators.

The Gish Reliance™ Oxygenator has technological characteristics which are substantially equivalent to

the COBE Optima Oxygenators and the Sorin *MONOLYTH* Oxygenators. The design, construction, materials and nominal specifications of the Gish Reliance™ Oxygenator are either identical or substantially equivalent to COBE *Optima* Oxygenators or Sorin *MONOLYTH* Oxygenators.

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In addition to the above assessment of intended use and technological characteristics, Gish Biomedical, Inc. has provided additional information to support substantial equivalence of the Gish Reliance™ Oxygenator. This includes biocompatibility testing on sterilized product and various in-vitro bench testing on sterilized and aged product. These data support that the Gish Reliance™ oxygenator does not significantly affect safety and effectiveness and is substantially equivalent to other marketed oxygenators.