

SUMMARY OF SAFETY AND EFFECTIVENESS

K 962641

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DEVICE NAME

MAXIMA FORTÉ™ Hollow Fiber Oxygenator with Plasma Resistant Fiber (Model:MAX-FTE)

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

- MAXIMA PLUS™ PRF Hollow Fiber Oxygenator with Improved Plasma Resistant Fiber (K941473)
- BARD® WILLIAM HARVEY® HF-5000 Membrane Oxygenator (K872107).

DESCRIPTION OF DEVICE

The Medtronic MAXIMA FORTÉ™ Hollow Fiber Oxygenator with Plasma Resistant Fiber is a single use, disposable, sterile, nonpyrogenic, gas exchange device with a self contained, venous side heat exchanger for regulating blood temperature. The MAXIMA FORTÉ™ oxygenator consists of a polycarbonate outer case which incorporates an oxygenator fiber bundle and a self contained heat exchanger. The fiber bundle is separated from the self contained heat exchanger by a polycarbonate housing. The static priming volume of the oxygenator blood path is approximately 295 ml. The oxygenator is designed to operate at blood flow rates between 1 - 7 liters per minute for periods up to 6 hours.

The MAXIMA FORTÉ™ oxygenator is placed in the cardiopulmonary bypass extracorporeal circuit for gas exchange. Venous blood enters the bottom of the oxygenator and flows through the nonporous polypropylene hollow tubes of the heat exchanger. These nonporous polypropylene hollow tubes are supported on their exterior by a polypropylene screen and contained within the polycarbonate heat exchanger housing. The polypropylene tubes run vertically through the polycarbonate chamber of the heat exchanger. The walls of these tubes provide a barrier between the venous blood and the cooling/warming water.

The flow of venous blood and water through the MAXIMA FORTÉ™ Heat Exchanger portion of the oxygenator is as follows:

Venous Blood

Venous blood enters the blood inlet port on the bottom/center of the oxygenator. This blood flows up through the polypropylene nonporous hollow tubes, exits the top of the tubes and flows radially into the outer polycarbonate housing containing the microporous fiber bundle.

Water

The cooling/warming water enters the water inlet port. The water is directed towards the top of the heat exchanger, then flows downward passing around the outside walls of the nonporous polypropylene tubes, then exits through the water outlet port. The water outlet and inlet ports are located on the side of the oxygenator parallel to each other.

Heat exchange in the oxygenator occurs as the venous blood passes through the nonporous hollow tubes, while the temperature regulated cooling/warming water passes around the outside walls of the same tubes. The venous blood is cooled/ warmed as it flows through the heat exchanger prior to entering the outer polycarbonate case containing the microporous hollow fiber bundle (oxygenation portion of the oxygenator).

The flow of blood and gas through the MAXIMA FORTÉ™ oxygenation portion of the oxygenator is as follows:

Blood

Venous blood (oxygen depleted) exits from the top of the heat exchanger chamber and flows radially outward while passing into the outer polycarbonate case, which contains microporous polypropylene hollow fibers. These fibers have been wound around a plastic core to produce a fiber bundle. This fiber bundle is encased in a clear polycarbonate case. The venous blood enters the fiber bundle and flows around the microporous polypropylene fibers. As blood flows over the microporous hollow fibers carbon dioxide/oxygen gas exchange occurs. Oxygenated arterial blood exits through the blood outlet port on the side of the oxygenator.

Gas

Gas enters through the gas inlet port on the top of the oxygenator and passes through the inside of the microporous hollow fibers. As the gas flows through the microporous hollow fibers gas transfer occurs. The gas exits from the gas outlet port on the side near the bottom of the oxygenator. Gas vents are located on the bottom of the oxygenator to prevent over-pressurization and under-pressurization.

Gas exchange (transfer) occurs by diffusion of carbon dioxide and oxygen, across the wall of the microporous hollow fiber membrane between the blood and gas phases. When blood passes over the exterior of the microporous hollow fibers, while gas passes through these same fibers, gas

exchange occurs. The blood is oxygenated and carbon dioxide removed as the blood flows over the fibers prior to exiting from the oxygenator to the patient.

STATEMENT OF INTENDED USE

MAXIMA FORTÉ™ Hollow Fiber Oxygenator with Plasma Resistant Fiber is indicated for use in procedures requiring the extracorporeal oxygenation of and carbon dioxide removal from blood and is designed to operate at blood flow rates between 1 and 7 liters per minute for periods up to six hours.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The MAXIMA PLUS™ PRF Hollow Fiber Oxygenator with Improved Plasma Resistant Fiber (Model Number: MAX-PRF) is indicated for use in procedures requiring the extracorporeal oxygenation of and carbon dioxide removal from blood during cardiopulmonary bypass and is designed to operate at blood flow rates between 1 and 7 LPM for periods up to six hours.

The BARD® WILLIAM HARVEY® HF-5000 Membrane Oxygenator provides blood oxygen and carbon dioxide gas transfer. In addition, it provides heat exchange in order to maintain or adjust the blood temperature as desired.

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

A table comparing the intended use and technological characteristics of the Medtronic Cardiopulmonary MAXIMA FORTÉ™ Hollow Fiber Oxygenator with Plasma Resistant Fiber with the two noted substantially equivalent devices is provided in Attachment 1. In addition, information regarding technological characteristic comparison is provided in the following section, "Determination of Substantial Equivalence".

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

In determining substantial equivalence of the MAXIMA FORTÉ™ Hollow Fiber Oxygenator with Plasma Resistant Fiber (Model: MAX-FTE), the decision-making process follows the 510(k) "Substantial Equivalence" flow diagram as follows:

The MAXIMA FORTÉ™ Hollow Fiber Oxygenator with Plasma Resistant Fiber (Model: MAX-FTE). is being "compared to the following two Marketed Devices"

- MAXIMA PLUS™ PRF Hollow Fiber Oxygenator with Improved Plasma

- Resistant Fiber (K941473)
- BARD® WILLIAM HARVEY® HF-5000 Membrane Oxygenator (K872107).

The MAXIMA FORTÉ™ Hollow Fiber Oxygenator with Plasma Resistant Fiber (Model: MAX-FTE). has the “same indications statement and intended uses” as the

- MAXIMA PLUS™ PRF Hollow Fiber Oxygenator with Improved Plasma Resistant Fiber (K941473)

The MAXIMA FORTÉ™ Hollow Fiber Oxygenator with Plasma Resistant Fiber (Model: MAX-FTE). has “new technological characteristics (e.g., design, materials and manufacturing processes)” from the currently Medtronic adult oxygenators. These technological characteristics include;

- Polypropylene heat exchanger
- Transparent polycarbonate housing
- Lower priming volume (~295 ml)
- Blood flow bottom to top heat exchanger, then top to bottom fiber bundle
- Microporous hollow fiber has a smaller inner diameter

These technological characteristics are common to other adult oxygenators currently in commercial distribution as follows;

- Plastic heat exchanger - BARD® WILLIAM HARVEY® HF-5000 Membrane Oxygenator (K872107).
- Transparent polycarbonate housing - BARD® WILLIAM HARVEY® HF-5000 Membrane Oxygenator (K872107).
- Lower priming volume (~270 ml) - Terumo Medical Corporation Capiiox SX Hollow Fiber Oxygenator (K922799).
- Blood flow bottom to top heat exchanger, then top to bottom fiber bundle - AVECOR Cardiovascular Affinity Hollow Fiber Oxygenator (K932252).
- Microporous hollow fiber has a smaller inner diameter - Inner diameter of microporous hollow fiber for other non-Medtronic adult oxygenators is unknown. Data demonstrates that this new technological characteristic does not present any new types of safety or effectiveness questions.

These technological characteristics “could affect the safety and effectiveness of the device”. However these “new technological characteristics do not raise new types of safety or effectiveness questions”. In addition, “there are accepted scientific methods which exist for assessing effects of these new technological characteristics”. These scientific methods are provided in the following oxygenator standards;

- ISO/DIS 7199 (ISO/TC 150/SC 2) 1995 Draft International Standard titled “Cardiovascular implants and artificial organs - Blood-gas exchangers”
- BG7199-1996 (proposed new American National Standard) titled, “Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)”

“Performance data to assess the effects of these new technological characteristics” has been performed. These “performance data demonstrate” that the MAXIMA FORTÉ™ Hollow Fiber Oxygenator with Plasma Resistant Fiber is substantially equivalent to marketed devices.

In addition, the modes of operation of the MAXIMA FORTÉ™ Hollow Fiber Oxygenator with Plasma Resistant Fiber are either identical or substantially equivalent to other hollow fiber oxygenators currently in commercial distribution. The function of the Medtronic MAXIMA FORTÉ™ Hollow Fiber Oxygenators is the extracorporeal oxygenation of and carbon dioxide removal from blood during cardiopulmonary bypass. The MAXIMA FORTÉ™ Hollow Fiber Oxygenators are designed to operate at blood flow rates between 1 and 7 LPM for periods up to six hours.

The predicate/marketed device is:

- MAXIMA PLUS® PRF Hollow Fiber Oxygenator with Improved Plasma Resistant Fiber (K941473)

A table comparing the intended use and technological characteristics of the MAXIMA FORTÉ™ Hollow Fiber Oxygenator with Plasma Resistant Fiber with the two noted substantially equivalent devices is provided in Attachment 1.

The biocompatibility testing and in-vitro bench testing demonstrated that when compared to the predicate devices the MAXIMA FORTÉ™ Hollow Fiber Oxygenator with Plasma Resistant Fiber do not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed hollow fiber oxygenators. The in-vitro bench testing included analysis of:

- Blood pathway integrity
- Heat exchanger pathway integrity
- Blood volumes
- Connectors
- Oxygenator and Carbon Dioxide Transfer Rates
- Heat Exchanger Performance Factor
- Blood Cell Damage
- Time Dependent Performance Changes
- Pressure Drop