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510(K) SUMMARY
(Summary of Information Respecting Safety and Effectiveness) K961836

COMPANY AND CONTACT PERSON

Medtronic, Inc.
Cardiopulmonary Division
4633 E. La Palma Avenue
Anaheim, CA 92807
714-779-3700 (phone)
714-779-7964 (fax)

Debra J. Kridner, Manager
Regulatory Affairs

DEVICE NAME

MAXIMA FORTÉ™ Hardshell Venous Reservoir
(FT-HSVR)

CLASSIFICATION NAME

Reservoir, Blood, Cardiopulmonary Bypass

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

- Medtronic MAXIMA® Hardshell Venous Reservoir (K933496)
- Medtronic MAXIMA® Filtered Hardshell Venous Reservoir (K891230 and K932254)
- Terumo Medical Corporation CAPIOX SX Hardshell Venous Reservoir (K922799)
- Avecor Cardiovascular AFFINITY CVR Cardiotomy/Venous Hardshell Reservoir (K936003)

DESCRIPTION OF DEVICE

The Medtronic MAXIMA FORTÉ™ Hardshell Venous Reservoir is a single use, disposable, sterile and nonpyrogenic fluid path device. Venous blood is collected and defoamed while cardiotomy blood is collected, defoamed and filtered prior to mixing with the venous blood.

The Medtronic MAXIMA FORTÉ™ Hardshell Venous Reservoir consists of a polycarbonate housing which incorporates a filter/defoamer assembly. The filter/defoamer assembly, which consists of polyurethane defoamers, a 20 micron (nominal) polyester filter and a styrene frame, is designed to defoam and filter cardiotomy blood and defoam venous blood.

The maximum capacity of the MAXIMA FORTÉ™ Hardshell Venous Reservoir is approximately 4,000 ml. The reservoir housing tapers toward the blood outlet port. The hardshell venous reservoir operates at venous blood flow rates from 1 to 7 liters per minute and cardiotomy blood flow rates from 1 to 5 liters per minute. Following intraoperative use, these reservoirs are used for the collection and autotransfusion of shed blood.

Venous Blood Flow

Venous blood enters the top of the reservoir through the venous inlet port. The venous blood flows downward through a central tube to the bottom of the filter/defoamer frame where it passes through the venous defoamer and outer defoamer into the main chamber of the reservoir.

Cardiotomy Blood Flow

Cardiotomy blood enters through any of the six (6) inlet cardiotomy ports. The intrathoracic suctioned cardiotomy blood flows downward through the center chamber of the cardiotomy filter/defoamer assembly, and passes through the defoamers and filter into the main chamber of the reservoir. The center chamber is separate from and surrounds the central tube through which the venous blood flows.

The venous and cardiotomy blood are mixed outside the filter/defoamer assembly, in the main chamber of the reservoir and in the low-volume, tapered area at the bottom of the reservoir. The filtered, defoamed and mixed blood then exits through the outlet port at the bottom of the reservoir.

The lid of the MAXIMA FORTÉ™ Hardshell Venous Reservoir contains various access ports, which include:

- one (1) 1/2" venous inlet port with temperature probe and luer port
- six (6) cardiotomy suction inlet ports,
  - three (3) - 1/4"
  - two (2) - 3/8"
  - one (1) - combination 1/4-3/8"
- two (2) filtered luer ports,
- two (2) unfiltered luer ports,
- one (1) recirculation inlet port, and
- one (1) vent port

The venous inlet port and cardiotomy inlet ports are mounted on a rotatable turret that allows the clinician optimal positioning during set-up and use. In addition, for ease of use the venous inlet 1/2" port may be converted to a 3/8" port by using a molded adaptor. The reservoir lid also has a;

- three-way stopcock sampling manifold, one-way check valve, and venous blue)/arterial (red) coiled sampling lines,
- a 3/8" recirculation line, and
- a built-in two-way pressure relief valve that is designed to relieve either high positive or low negative pressures.

A 3/8" blood outlet port is located at the bottom of the device.

STATEMENT OF INTENDED USE

The MAXIMA FORTÉ™ Hardshell Venous Reservoir is intended for use in procedures requiring the storage and filtration of blood in the extracorporeal circuit during cardiopulmonary bypass. The MAXIMA FORTÉ™ Hardshell Venous Reservoir is also intended for use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for volume replacement.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

Medtronic MAXIMA® Hardshell Venous Reservoir (MHR-T) - in procedures requiring the storage and filtration of blood in the extracorporeal circuit during cardiopulmonary bypass.

Medtronic MAXIMA® Filtered Hardshell Venous Reservoir (1315) - in procedures requiring the storage and filtration of blood in the extracorporeal circuit during cardiopulmonary bypass and for use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for volume replacement..

Terumo Medical Corporation CAPIOX SX Hardshell Venous Reservoir - to be used during open heart surgical procedures requiring cardiopulmonary bypass for periods up to 6 hours.

Avecor Cardiovascular AFFINITY CVR Cardiotomy/Venous Hardshell Reservoir - To be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

A table comparing the intended use and technological characteristics of the Medtronic Cardiopulmonary MAXIMA FORTÉ™ Hardshell Venous Reservoirs with the four noted substantially equivalent devices is provided in Attachment I.

A table comparing the intended use and technological characteristics of the Medtronic Cardiopulmonary MAXIMA FORTÉ™ Hardshell Venous Reservoirs with the four noted substantially equivalent devices is provided in Attachment I.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

The Medtronic Cardiopulmonary MAXIMA FORTÉ™ Hardshell Venous Reservoirs are substantially equivalent to other hardshell venous reservoirs currently in commercial distribution. These predicate/marketed devices include:

- Medtronic MAXIMA® Hardshell Venous Reservoir (K933496)
- Medtronic MAXIMA® Filtered Hardshell Venous Reservoir (K891230 and K932254)
- Terumo Medical Corporation CAPIOX SX Hardshell Venous Reservoir (K922799)
- Avecor Cardiovascular AFFINITY CVR Cardiotomy/Venous Hardshell Reservoir (K936003)

The Medtronic Cardiopulmonary MAXIMA FORTÉ™ Hardshell Venous Reservoirs have an intended use which is substantially equivalent to other hardshell venous reservoirs currently in commercial distribution These predicate/marketed devices include:

- Medtronic MAXIMA® Hardshell Venous Reservoir (K933496) - indicated for only intraoperative use.
- Medtronic MAXIMA® Filtered Hardshell Venous Reservoir (K891230 and K932254) indicated for intraoperative and postoperative use.
- Terumo Medical Corporation CAPIOX SX Hardshell Venous Reservoir (K922799) - indicated for only intraoperative use.
- Avecor Cardiovascular AFFINITY CVR Cardiotomy/Venous Hardshell Reservoir (K936003) - indicated for only intraoperative use.

The Medtronic Cardiopulmonary MAXIMA FORTÉ™ Hardshell Venous Reservoirs have technological characteristics which are substantially equivalent to other hardshell venous reservoirs currently in commercial distribution. These predicate/marketed devices include:

- Medtronic MAXIMA® Hardshell Venous Reservoir (K933496)
- Medtronic MAXIMA® Filtered Hardshell Venous Reservoir (K891230 and K932254)
- Terumo Medical Corporation CAPIOX SX Hardshell Venous Reservoir (K922799)
- Avecor Cardiovascular AFFINITY CVR Cardiotomy/Venous Hardshell Reservoir (K936003)

The design, construction, materials and nominal specifications of the Medtronic Cardiopulmonary MAXIMA FORTÉ™ Hardshell Venous Reservoirs are either identical or substantially equivalent to other hardshell venous reservoirs currently in commercial distribution. These predicate/marketed devices include:

- Medtronic MAXIMA® Hardshell Venous Reservoir (K K933496)
- Medtronic MAXIMA® Filtered Hardshell Venous Reservoir (K891230 and K932254)
- Terumo Medical Corporation CAPIOX SX Hardshell Venous Reservoir (K922799)
- Avecor Cardiovascular AFFINITY CVR Cardiotomy/Venous Hardshell Reservoir (K936003)

In addition, the in-vitro testing demonstrated that when compared to a predicate device the MAXIMA FORTÉ™ Hardshell Venous Reservoirs do not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed hardshell venous reservoirs. The testing included analysis of:

- Breakthrough Volume Testing
- Blood Trauma Testing
- Static Hold-Up Volume Testing
- Pressurization Testing
- Filtration Efficiency Testing
- Dynamic Hold-Up Volume Testing
- Cleanliness

Attachment I

DEVICE COMPARISONS -- GENERAL CHARACTERISTICS AND NOMINAL SPECIFICATIONS

	Medtronic, Inc. MAXIMA FORTE™ Hardshell Venous Reservoir	Medtronic, Inc. MAXIMA® Hardshell Venous Reservoirs	Terumo Medical Corporation CAPIOX SX Hardshell Venous Reservoir	Avecor Cardiovascular AFFINITY CVR Cardiotomy Venous Hardshell Reservoir
510(k) Number:	This submission	K891230 and K932254 K933296	K922799	K936003
Catalog Number(s):	FT-HSVR	1315 (K891230 and K932254) MHR-T (K933496)	CX*SXXX	CVR
Intended Use:	In procedures requiring the storage and filtration of blood in the extracorporeal circuit during cardiopulmonary bypass. For use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for volume replacement.	1315 and MHR-T In procedures requiring the storage and filtration of blood in the extracorporeal circuit during cardiopulmonary bypass. 1315 For use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for volume replacement.	To be used during open heart surgical procedures requiring cardiopulmonary bypass for periods up to 6 hours.	To be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary bypass procedures up to 6 hours in duration.
Performance Characteristics:				
Duration of Use (Maximum)	6 hours	6 hours	6 hours	6 hours
Blood Flow Rate (Maximum)				
Venous (lpm)	7	7	4	7
Cardiotomy (lpm)	5	6	4	6
Filtration				
Cardiotomy Filter	20 micron depth filter	20 micron depth filter	20 micron depth filter	30 micron depth filter

Attachment I

DEVICE COMPARISONS -- GENERAL CHARACTERISTICS AND NOMINAL SPECIFICATIONS

	Medtronic, Inc. MAXIMA FORTE™ Hardshell Venous Reservoir	Medtronic, Inc. MAXIMA® Hardshell Venous Reservoirs	Terumo Medical Corporation CAPIOX SX Hardshell Venous Reservoir	Avecor Cardiovascular AFFINITY CVR Cardiotomy Venous Hardshell Reservoir
Technological Characteristics:				
Filter/Defoamer Assembly				
Filter				
Material	Polyester	Polyester	Polyester	Polyester
Type	Depth	Depth	Depth	Depth
Defoamer				
Material	Polyurethane Foam	Polyurethane Foam	Polyurethane Foam	Polyurethane Foam
Reservoir				
Design and Construction				
System	Open Circuit	Open Circuit	Open Circuit	Open Circuit
Volume Capacity (ml)	4000	3800	3000	4000
Minimum Operating Level (ml)	500	300	100	500
Filter/Defoamer	Integrated within reservoir	Integrated within reservoir	Integrated within reservoir	Integrated within reservoir
Materials	Polycarbonate	Polycarbonate	Polycarbonate	Not stated
Ports/Inlets				
Venous Blood Inlet	Yes	Yes	Yes	Yes
Blood Outlet	Yes	Yes	Yes	Yes
Cardiotomy Suction Inlet/Ports	Yes	Yes	Yes	Yes
Prime Ports	Yes	Yes	Yes	Yes
Luer and Vent Ports	Yes	Yes	Yes	Yes
Rotatable Turret/Venous Inlet	Yes	No	Yes	Yes
Sample Manifold - 3 Gang	Yes	No	Yes	Yes

Attachment I

DEVICE COMPARISONS -- GENERAL CHARACTERISTICS AND NOMINAL SPECIFICATIONS

	Medtronic, Inc. MAXIMA FORTE™ Hardshell Venous Reservoir	Medtronic, Inc. MAXIMA® Hardshell Venous Reservoirs	Terumo Medical Corporation CAPIOX SX Hardshell Venous Reservoir	Avecor Cardiovascular AFFINITY CVR Cardiotomy Venous Hardshell Reservoir
Technological Characteristics:				
Oxygenator/Hardshell Venous Reservoir May Be Coupled	Yes	Yes	Yes	Yes
Hardshell Venous Reservoir Mode of Operation	To collect and defoam venous blood while cardiotomy blood is collected, defoamed and filtered prior to mixing with the venous blood. The defoamed/ filtered blood is then returned to the patient.	To collect and defoam venous blood while cardiotomy blood is collected, defoamed and filtered prior to mixing with the venous blood. The defoamed/ filtered blood is then returned to the patient.	To collect and defoam venous blood while cardiotomy blood is collected, defoamed and filtered prior to mixing with the venous blood. The defoamed/ filtered blood is then returned to the patient.	To collect and defoam venous blood while cardiotomy blood is collected, defoamed and filtered prior to mixing with the venous blood. The defoamed/ filtered blood is then returned to the patient.