K984322

510(k) Safety and Effectiveness Summary

1. Submitted by:

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P.O. Box 87
41037 Mirandola (MODENA)
Italy

Telephone number: 01139 0535 29811

3 Date of Preparation:

December 2, 1998

4 Name and Address of Owner/Operator and Manufacturer

Dideco, S.p.A.
via Statale 12 Nord, 86
P.O. Box 87
41037 Mirandola (MODENA)
Italy

5 Product Name

Trade Name: D 920, Lilliput 1 twin reservoir

Common Name: Infant-newborn Venous Cardiotomy Reservoir

6. Predicate Devices

1) VENOMIDICARD/MIDICARD D752/D762 manufactured by:

Dideco S.p.A..
Via Statale 12 Nord, 86
41037 Mirandola (MO) ITALY

K941215, cleared on May 5, 1995

2) MICRO SAFE manufactured by:

Polystan A/S
Walgerholm 8
3500 Vaerlose DENMARK

K953976, cleared on February 4, 1997

7. Claim of Substantial Equivalence

The D 920 is an infant/newborn hard-shell venous reservoir, like the predicate devices. The basic function of all hardshell reservoirs is the same. They store the blood coming from the surgical theater, draw it from the venous reservoir and push it through an oxygenator via an external pump. The operating principles and control mechanisms are exactly the same for the D 920 and the predicate devices.

As both the Venomidicard and the D 920 are manufactured by Dideco, they share the same incoming raw materials inspections, manufacturing in process controls and final controls; in addition the D 920 utilizes the same material type and a similar blood flow path as the Venomidicard and the filtration sequence is the same for D 920 and Venomidicard.

The indications for use are the same for both D 920, Micro safe and Venomidicard: all devices are intended for the infant population who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation.

All predicate devices have a bayonet/YSI 400 compatible temperature probe.

Substantial Equivalence Comparison Chart: Performance Characteristics

Parameters	VENOMIDICARD/ MIDICARD	MICRO-SAFE	D 920
Manufacturer	Dideco S.p.A.	Polystan A/V.	Dideco S.p.A.
Method of sterilization	Ethylene Oxyde	Ethylene Oxyde	Ethylene oxide
Maximum blood flow rate	4 LPM	0.8 LPM	1.5 LPM
Recommended operating blood flow rate	4000 ml/min	800 ml/min	800 ml/min
Filtering pore size	20 micron	40 micron	30 micron

Substantial Equivalence Comparison Chart: General features

Parameters	VENOMIDICARD/ MIDICARD	MICRO-SAFE	D 920
Connections:			
Venous return	3/16"	3/16" - 1/4"	3/16" - 1/4"
Venous outlet	3/8"	3/16" - 1/4"	3/16" - 1/4"
Cardiotomy inlet	3/16" - 1/4"	3/16" - 1/4"	3/16" - 1/4"
Reservoir venous inlet	3/8"	1/4"	1/4"
Filter materials:			
Cardiotomy filter	polyester 20 microns	polyester 40 microns	polyester 30 microns
Reservoir filter	polyurethane	polyurethane	polyurethane
Screen filter	polyester 120 microns	polyester 175 microns	polyester 120 microns
Available configuration	Card. /venous reservoir	Venous reservoir	Card. /venous reservoir
Housing:			
type	rigid hardshell	rigid hardshell	rigid hardshell
material	polycarbonate	polycarbonate	polycarbonate
max. volume	2000 ml	400 ml	700 ml
Packaging:			
type	Single/multi unit box	single/multi unit box	single/multi unit box
material	Tyvek pouch/carton box	Tyvek pouch/carton box	Tyvek pouch/carton box
Patient population	Children	Infants	Infants

8. Device Description

The D 920 serves as a collection reservoir for venous blood and for blood recovered by intracardiac sucker and ventricular vent devices. The D 920 device can also be attached to an oxygenator, previously cleared by the Agency for the same patient population, in order to collect blood during normal operations, assuring the proper oxygenation capability of the device. This device is currently being developed in an open system configuration which includes the Dideco D901 Lilliput oxygenator, cleared by the Agency on March 15th 1996 (K953835).

The hard-shell cardiotomy/venous reservoirs are comprised of a rigid polycarbonate housing with an internal support; in which a filtering system is placed around the support. The D 920 has two distinct (upper and lower) sections connected by an overflow system. The upper section contains a defoamer sponge and screen filter which are designed to remove microaggregates and microemboli from cardiotomy suction and vent blood. The devices are available with a 30 micron filter. The venous return blood enters the lower section and passes through a defoamer sponge. Only the lower section is contained within a polyester outer screen.

The D 920 has four cardiotomy suction/vent inlet ports which accommodate both 1/4 and 3/16" inner diameter tubing. Three priming ports are positioned on the top of the reservoir: 3 x luer lock (filtered), 1 x luer lock (unfiltered) and 1 x 1/4-3/16". Fluid added through the one outer priming port bypasses the integral cardiotomy section. Fluids added through the three inner luer and 1/4-3/16" ports flow through the defoamer and filter elements in the cardiotomy section. Venous blood enters through the 1/4-3/16" inlet port at the bottom of the unit. The D 920 has a 1/4-3/16" blood outlet port at the bottom of the unit. The 1/4" gas outlet port is located at the top of the unit. Both devices are supported by a holder.

9. Intended Use

The Dideco D 920 is intended for use in infants who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation (ECC) for whom a low circuit priming volume is required. The venous reservoir with cardiotomy filter is intended for use as a storage reservoir (gravity or vacuum-assisted) for venous return blood and as a filtered reservoir for cardiac suction during ECC. The cardiotomy reservoir has the same intended use as the venous reservoir above mentioned as a filtered reservoir for cardiac suction blood in a bypass extracorporeal circuit, but does not have a venous return.

Following intraoperative use, the reservoirs are used for the collection and autotransfusion of shed blood.

10. Summary of Nonclinical Data

The Dideco D 920 has successfully completed the full range of biocompatability testing as specified in ISO 10993-1:1992 and FDA May 1, 1995 Memorandum on the use of the ISO 10993 standard for Biocompatibility Testing. Dideco has also successfully performed *in vitro* performance testing on the D 920 based on the ISO 7199 international standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 2 1999

Dideco, S.P.A.
c/o Mr. Barry Sall
Senior Regulatory Consultant
Parexel International Corporation
1601 Trapelo Road
Waltham, MA 02154

Re: K984322
Dideco D920, Lilliput 1 Twin Reservoir
Regulatory Class: II (Two) and III (Three)
Product Code: DTN and DTP
Dated: December 2, 1998
Received: December 3, 1998

Dear Mr. Sall:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 984322

Device Name: Dideco D920, Lilliput 1 twin reservoir

Indications for Use:

The Dideco D920, Lilliput 1 twin reservoir is intended for use in infants who undergo cardiopulmonary bypass surgery requiring extracorporeal circulation for whom a low circuit priming volume is required. The venous reservoir with cardiotomy filter is intended for use as a storage reservoir (gravity or vacuum-assisted) for venous return blood and as a filtered reservoir for cardiac suction during ECC. The cardiotomy reservoir has the same intended use as the venous reservoir, as a filtered reservoir for cardiac suction blood in a bypass extracorporeal circuit, but does not have a venous return. Following intraoperative use, the reservoirs are used for the collection and autotransfusion of shed blood.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K984322

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use_____

(Optional format 1-2-96)