

OCT 30 1986 K954850



**510(k) SUMMARY FOR THE BARD® WILLIAM HARVEY®  
HF-6000 MEMBRANE OXYGENATOR**

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of SMDA 1990.

The Bard® William Harvey® HF-6000 Membrane Oxygenator is a single use gas exchange device with an integral venous side heat exchanger. Venous blood is pumped into the stainless steel heat exchanger, then is directed over the gas exchange hollow fibers. Oxygen and carbon dioxide transfer occur by diffusion as gas flows through the hollow fibers.

This product will have the following indications:

The HF-6000 Oxygenator provides the gas exchange and temperature regulating capacity required to support a patient undergoing a cardiopulmonary bypass procedure for a period of up to six (6) hours.

The predicate devices for this 510(k) Notification are:

- 1) Medtronic MAXIMA® Hollow Fiber Oxygenator (K920889)
- 2) Sarns™ Turbo Membrane Oxygenator (K903436)

Based on a review of FOI-released copies of 510(k) #K920889 and the 510(k) summary for 510(k) #K941653 (which makes reference to 510(k) #K903436), the Medtronic MAXIMA® Hollow Fiber Oxygenator and the Sarns™ Turbo Membrane Oxygenator appear to be covered by the 510(k)'s listed above.

The "510(k) Substantial Equivalence Decision-Making Process (Detailed)" decision tree (FDA 92-415. Premarket Notification 510(k): Regulatory Requirements for Medical Devices. Page 51) was utilized to make a determination of substantial equivalence as follows:

**1. Does New Device Have Same Indication Statements?**

**Yes.** The Bard® William Harvey® HF-6000 Membrane Oxygenator has the same indications as both the Medtronic MAXIMA® Hollow Fiber Oxygenator and the

Sarns™ Turbo Membrane Oxygenator. All of these devices provide the gas exchange and temperature regulating capacity required to support a patient undergoing a cardiopulmonary bypass procedure for a period of up to six (6) hours.

**2. Does New Device Have Same Technological Characteristics, e.g., Design, Materials, etc.?**

No. Although the Bard® William Harvey® HF-6000 Membrane Oxygenator, the Medtronic MAXIMA® Hollow Fiber Oxygenator and the Sarns™ Turbo Membrane Oxygenator have the same technological characteristics and many of the same materials, the Bard® William Harvey® HF-6000 Membrane Oxygenator does include some other materials and components which are different.

**3. Could the New Characteristics Affect Safety or Effectiveness?**

Yes. These different materials could result in changes in biocompatibility, safety, or performance.

**4. Do the New Characteristics Raise New Types of Safety or Effectiveness Questions?**

No. The materials used in the Bard® William Harvey® HF-6000 Membrane Oxygenator will raise the same questions concerning biocompatibility, safety and performance as those used in the predicate devices, including questions of cell damage, toxicity, etc.

**5. Do Accepted Scientific Methods Exist for Assessing Effects of the New Characteristics?**

Yes. Tests of performance and integrity for oxygenators are delineated in the ISO Draft International Standard 7199 (ISO/DIS 7199), "Cardiovascular implants and artificial organs - Blood-gas exchangers." In addition, an *ex vivo* animal test protocol was developed. Finally, the biocompatibility tests performed on the Bard® William Harvey® HF-6000 Membrane Oxygenator address the requirements of the International Standard ISO 10993, "Biological Evaluation of Medical Devices Part-1: Evaluation and Testing" and the FDA-modified testing matrix included in the ODE May 1, 1995 General Program Memorandum #G95-1.

**6. Are Performance Data Available to Assess Effects of New Characteristics?**

Yes. The Bard® William Harvey® HF-6000 Membrane Oxygenator, the Medtronic MAXIMA® Hollow Fiber Oxygenator (model 1380), and the Sarns™ Turbo

Membrane Oxygenator (model 9443) were compared for performance characteristics using the above-referenced ISO/DIS 7199.

In addition, the Bard® William Harvey® HF-6000 Membrane Oxygenator was subjected to integrity testing per the ISO/DIS 7199, *ex vivo* animal testing to assess its ability to sustain an animal on partial bypass, and biocompatibility testing to assess its safety.

**7. Performance Data Demonstrate Equivalence?**

**Yes.** The performance of the Bard® William Harvey® HF-6000 Membrane Oxygenator was equivalent to those of the predicate devices.

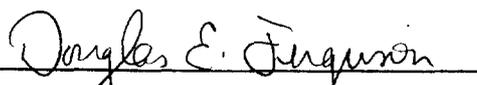
When tested in accordance with ISO/DIS 7199, the Bard® William Harvey® HF-6000 Membrane Oxygenator was substantially equivalent with respect to performance to the predicate devices. In addition, the Bard® William Harvey® HF-6000 Membrane Oxygenator met all criteria with respect to integrity when tested per the above-referenced ISO standard.

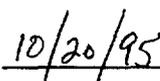
In animal testing, the Bard® William Harvey® HF-6000 Membrane Oxygenator demonstrated the ability to provide the gas exchange and body temperature regulating capacity required to support an animal undergoing a partial cardiopulmonary bypass procedure for a period of up to six hours. In this study, there were no meaningful observations with regard to clinical outcomes, physiological responses, hematological and serum chemistry parameters, gross pathology and histopathology that raise any concerns about the safety of the Bard HF-6000 oxygenator. It was concluded that the Bard device is fully safe and effective for use.

The Bard® William Harvey® HF-6000 Membrane Oxygenator passed all tests of biocompatibility required by the International Standard ISO 10993.

**SUBSTANTIALLY EQUIVALENT DETERMINATION:**

The Bard® William Harvey® HF-6000 Membrane Oxygenator is substantially equivalent to the predicate devices, the Medtronic MAXIMA® Hollow Fiber Oxygenator and the Sarns™ Turbo Membrane Oxygenator.

  
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