

K953821

## **BIOCOR™ 200 HARDSHELL VENOUS RESERVOIR**

### **510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION**

**Minntech Corporation has provided the following information to the US Food and Drug Administration to support that the Biocor™ 200 Hardshell Venous Reservoir is substantially equivalent to other devices currently in commercial distribution within the United States.**

#### **1. Comparison to Another Device in Commercial Distribution within the United States**

**The Biocor™ 200 Hardshell Venous Reservoir is comparable in regards to its intended use and technological characteristics to other device in commercial distribution within the United States. Minntech Corporation has compared the similarities and difference of the Biocor™ 200 Hardshell Venous Reservoir to the Affinity CVR Cardiotomy/ Venous Reservoir with filter (Avecor Cardiovascular) and the cardiopulmonary bypass indications of the Sorin HSVRF Hardshell Venous Reservoir with Integral Cardiotomy Filter (Sorin Biomedical). This comparison supported comparability with respect to intended use, design features, and product specifications.**

#### **2. Summary of Safety and Effectiveness**

##### **2.1 In-Vitro Performance Testing**

**Minntech Corporation has described the test plan for the Biocor™ 200 Hardshell Venous Reservoir and has provided the specific test results. The plan included a comparative analysis performance and structural integrity. Tests included volume calibration, dynamic priming volume, breakthrough volume, hold up volume, air removal/separation, particulate filtration efficiency, general performance assessment, and blood cell damage. Data support that the performance and integrity of the Biocor™ 200 Hardshell Venous Reservoir is suitable for its intended use and comparable to the Affinity CVR Cardiotomy/Venous Reservoir with filter (Avecor Cardiovascular) and the cardiopulmonary bypass indications of the Sorin HSVRF Hardshell Venous Reservoir with Integral Cardiotomy Filter (Sorin Biomedical).**

## **2.2 Biocompatibility Studies**

**Minntech Corporation has described the test plan for the Biocor™ 200 Hardshell Venous Reservoir and has provided the specific test results. The biocompatibility studies conducted were cytotoxicity, hemolysis, acute systemic, intracutaneous, sensitization AMES mutagenicity, in vitro hemocompatibility UPTT, PT, thrombosis formation and complement activation. Under the conditions of these studies, the Biocor™ 200 Hardshell Venous Reservoir was demonstrated to be non-cytotoxic, non-hemolytic, non-sensitizing, non-toxic and non-mutagenic. The Biocor™ 200 Hardshell Venous Reservoir is hemocompatible and has acceptable clotting time and complement activation profiles. Thrombosis formation was not detected. Based on these results, the Biocor™ 200 Hardshell Venous Reservoir is safe for use in cardiopulmonary bypass procedures.**

## **3. Summary of Substantial Equivalence**

**Minntech Corporation has provided the above information within the 510(k) Premarket Notification to support that the Biocor™ 200 Hardshell Venous Reservoir is safe and effective as a storage reservoir for venous blood and for blood recovered by intrathoracic suction. Additionally, the Biocor™ 200 Hardshell Venous Reservoir has been shown to be comparable to other devices currently in commercial distribution. Data and information provided within this 510(k) Premarket Notification adequately support that the Biocor™ 200 Hardshell Venous Reservoir is substantially equivalent to other devices currently in commercial distribution.**