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510(k) Summary
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1. Name and Address of Contact Person

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2. Name of Device:

Quick-Prime Hemoconentrators with Duraflo® Treatment
Models:
HQ-7000™ GOLD
HQ-7005™ GOLD with tubing set
HQ-7005L™ GOLD with tubing set with luer fittings

3. Predicate Device:

Quick-Prime Hemoconentrators
Models:
HQ-7000™
HQ-7005™ with tubing set
HQ-7005L™ with tubing set/male luer adapters

4. Device Description

The HQ-7000™ GOLD, HQ-7005™ GOLD, and HQ-7005L™ GOLD devices are coated with the Duraflo® Treatment. The Duraflo® Treatment may improve the blood compatibility of non-biological surfaces. Devices with this treatment are used when a heparin-treated blood path is desired. The Duraflo® Treatment provides a heparin-treated blood path containing up to 900 USP units of heparin on the hemoconcentrator.

The Quick-Prime Hemoconcentrator devices have a 1.25 m^2 total planar membrane area and a priming volume of approximately 81 mL. Hansen port caps are provided with the Quick-Prime Hemoconcentrator. A yellow adapter connector covers the upper port to allow for filtration. A white cap seals the port at the base of the device. The HQ-7005™ GOLD, and HQ-7005L™ GOLD devices contain pre-connected blood inlet and outlet tubing. Tubing is graduated in size with 1/4 inch (6.35 mm) I.D. ends that are ready for connection to the extracorporeal circuit. The HQ-7005L™ GOLD has male Luer fittings at each end for connection in the extracorporeal circuit.

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5. Intended Use

The Quick-Prime Hemoconcentrator is designed for use in cardiopulmonary bypass surgery to remove excess fluid and low molecular weight blood constituents from the extracorporeal circuit. It is also indicated for use for patients with acute or chronic fluid overload when conservative therapy is inadequate.

6. a. Technology Comparison

The proposed device and predicate device are essentially identical, with the only exception being associated with the addition of Duraflo® treatment to the blood-contacting surfaces of the treated devices. The components remain the same for both the treated and non-treated versions.

b. Testing Summary

The following studies were conducted to qualify the Quick-Prime Hemoconcentrators with Duraflo® Treatment:

- Prime Volume
- Leak Test
- Ultrafiltration Rate vs. Transmembrane Pressure Testing
- Blood Chemistry
- Generated Plasma Hemoglobin
- Blood Damage
- Heparin Leaching
- Heparin Quantitation

c. Rational for Substantial Equivalence Determination

The coated and uncoated versions of the Quick-Prime Hemoconcentrators are essentially identical. The basic materials remain the same, with the only exception being associated with the addition of the Duraflo® Treatment to the blood contacting surfaces of the treated versions.

Testing has demonstrated that units with the proposed addition of the Duraflo® Treatment are substantially equivalent to the predicate (uncoated) device, and that there were no adverse effects on overall hemoconcentrator performance.