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PREMARKET NOTIFICATION

VII: 510(K) SUMMARY

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Manufacturer: NAMIC U.S.A. Corporation
Glens Falls, New York 12801

Contact Person: Mary Meagher Rubin
Regulatory Affairs Specialist

Telephone Number (518) 798-0067
Facsimile Number (518) 798-5475

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Trade Name: NAMIC HEMO-Valve

Common Name: Adaptor

Classification Name: Cardiopulmonary Bypass adaptor, stopcock, manifold, or fitting.

Predicate Devices: NAMIC High Pressure Stopcock
NAMIC PTCA Y-Adaptor
Braun Safsite [Valve]

Product Description:

The HEMO-Valve consists of an elastomeric valve located between male and female luer lock fittings. The valve may be opened by connecting a male luer lock (the luer fitting pushes the gland out of the way) or may be opened by introducing a guidewire in a forward or backloading manner.

Intended Use:

The HEMO-Valve is recommended for use in angiographic procedures involving blood or other potentially infectious materials, so that the procedure can be performed in such a manner as to minimize blood loss and patient/user exposure to these substances. The HEMO-Valve is intended for use in intra-arterial and intravenous administration of fluids, including radiographic contrast media.

The HEMO-Valve is identical to currently marketed NAMIC devices NAMIC High Pressure Stopcock, NAMIC PTCA Y-Adaptor, and the NAMIC Hemostatic Introducer Sheath with respect to materials of construction. The manufacturing process for the HEMO-Valve is common to other products manufactured by NAMIC. Packaging, sealing, and sterilization for the HEMO-Valve is identical to that of all NAMIC devices.

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VII. 510(K) Summary (Continued).

The manner in which the normally closed valve is actuated (by insertion of a male luer lock) is the same as the predicate device.

The intended uses of the HEMO-Valve are consistent with those of the predicate devices.

As with all three predicate devices, the HEMO-Valve allows for syringe aspiration and Injection, its primary function, being an adaptor. Insertion and backloading of a guidewire in addition to hemostasis around a guidewire are functions the HEMO-Valve has in common with the NAMIC PTCA Y-Adaptor. Finally, as with the NAMIC High Pressure Stopcock, the HEMO-Valve is designed to withstand high pressure injections.

The HEMO-Valve has been subjected to non-clinical performance testing to provide data supporting the functional claims of the device. The test protocol included testing to confirm hemostasis during and after wire exchanges as well as with the valve in the vacant position. Hydrostatic and Dynamic pressure testing were performed to confirm the pressure rating of the device.

Biocompatibility testing has been performed on the NAMIC predicate devices. There are no changes regarding device material.