

**BMW Medical, Inc.'s Clamless Valved Catheter-Midline (CVC-ML)
Premarket Notification**

**510 K SUMMARY
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1. Submitted by:

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3. Device Identification:

Trade Name: CVC-Midline Catheter
Common Name: Peripheral Catheter (midline catheter)
Classification Name: Intravascular Catheter

4. Predicate Device(s):

C. R. Bard, Inc., Groshong Peripherally Inserted Central Venous Catheter and
HDC Corp.'s V-Cath® Midline Catheter.

5. Device Description:

BMW Medical has developed a midline catheter that provides the benefits of the valve incorporated at the distal tip of the Groshong PIC catheter on an open-ended midline catheter. The BMW valve is external to the central venous system and is protected inside the catheter adapter.

BMW Medical, Inc.'s midline catheters are single lumen catheters. They are composed of extruded silicone rubber tubing which is homogeneously mixed with barium sulfate (BaSO₄) prior to extrusion to impart radiopacity. The catheters vary in diameter to accommodate specific patient populations.

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A 2-piece plastic adapter is attached to the proximal end of each single lumen catheter. The catheter is mechanically locked onto the adapter with a silicone rubber sleeve. The other end of the adapter terminates in a female luer which allows attachment of the catheter to a male luer fitting.

The adapter houses a slitted disc of silicone rubber which serves as a three-way valve. The valve remains closed when the catheter is not in use. The valve opens inward toward the distal tip of the catheter when fluids are infused into the patient via the catheter, and it opens outward toward the female luer of the proximal hub during aspiration of blood samples.

6. Intended Use:

BMW's CVC Midline catheter is designed to establish peripheral venous access for administration of fluids including, but not limited to, hydration agents, antibiotics, analgesics, and blood products. It is also indicated for blood specimen withdrawal.

This product is effective for venous access in adults, children, and infants who require peripheral intravenous therapy.

7. Summary of Technological Characteristics of Device in relation to Predicate Device(s):

BMW Medical, Inc. has developed a midline catheter that provides the benefits of the valve incorporated at the distal tip of Groshong catheters on an open-ended midline catheter similar to the V-Cath® Midline marketed by HDC Corp. The BMW valve is external to the central venous system and is protected inside the catheter adapter. This configuration provides the advantages of a normally closed three-way valve while avoiding the influences of continuous direct blood contact that can potentially interfere with the function of valves positioned in the vasculature.

BMW's CVC midlines are trimmed from the distal end, whereas the Groshong catheters are trimmed from the proximal end, necessitating final attachment of the Groshong catheter to the hub by the user.

Because the BMW valve is located in the CVC Midline hub, use of a stylet stiffener or guide wire during catheter placement requires that the stiffener or guide wire pass through the valve. Studies have shown that repeated insertion and removal of the guide wires or stylet through the valve does not compromise its function.

The BMW CVC Midline incorporates fixed suture wings (predicate devices have removable suture wings) and integral extension tubing. Because the extension tubing is attached to the BMW CVC Midlines, the priming volume of the BMW catheter is greater than that of the predicate devices.

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BMW's midline catheter adapter (hub) is fabricated from a medical grade plastic that is not identical to that of the predicate devices. This medical grade material has been used on legally marketed devices for purposes identical to those intended for BMW's CVC Midline catheters.

8. Assessment of Performance Data used to justify Substantial Equivalence Claim

The primary advantages afforded by valved catheters are that they reduce the potential for air embolism and bleedback. Performance data indicate that the valve included in the hub of the BMW CVC Midline catheter is at least as effective in minimizing these potentials as are the predicate devices, even when a guide wire or stylet stiffener is passed through the valve. In addition, no hemolysis of blood is observed when aspirating blood through BMW's valve, and aspiration pressures are low.

Published biocompatibility flow chart requirements indicate that BMW's hub material meets biocompatibility requirements, and is therefore acceptable for use in this catheter application.

Further, test data collected on the stiffness, elongation at break, radiopacity, flow rate, and tensile and burst strength of the catheter, valve function, and leak test data demonstrate that the BMW CVC Midline is substantially equivalent to the predicate HDC V-Cath® Midline and Bard Groshong PIC catheters.

Based on the above and physical comparisons, the BMW CVC Midline catheter is substantially equivalent to a device combining the performance characteristics of the valved Bard Groshong PIC catheter with the physical performance of HDC's V-Cath® Midline catheter.

9. Conclusion

BMW's CVC Midline catheters are substantially equivalent to a device combining the performance characteristics of the valved Bard Groshong PIC catheter with the physical performance of HDC's V-Cath® Midline catheter.