

**BMW Medical, Inc.'s Multi-Lumen Clampless Valved Catheter-Tunneled
(CVC-Tunneled) Premarket Notification**

510 K SUMMARY

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3. Device Identification:

Trade Name: Clampless Valved Catheter-Tunneled (CVC-T)
Common Name: Multi-lumen Central Venous Catheter
Classification Name: Intravascular Catheter, Long-term

4. Predicate Device(s):

Bard Access Systems, Inc., (Bard) Groshong Multi-Lumen Central Venous
Catheters and Hickman Multi-Lumen Central Venous Catheters.

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5. Device Description:

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

BMW Medical, Inc.'s multi-lumen catheters are composed of extruded silicone rubber tubing which is homogeneously mixed with barium sulfate ($BaSO_4$) prior to extrusion to impart radiopacity. The catheters vary in diameter and number of lumens to accommodate specific applications.

A silicone rubber joint permanently attaches the multi-lumen catheter tubing to the 2 or 3 legs required to access each lumen of a dual or a triple lumen catheter. A 2-piece rigid plastic adapter is attached to the proximal end of each single lumen leg. Each leg is mechanically locked onto the barbed end of the adapter with a silicone rubber sleeve. The other end of the adapter terminates in a female luer which allows for 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 toward the distal tip of the catheter when fluids are infused into the patient via the catheter, and it opens toward the female luer of the proximal hub during aspiration of blood samples.

6. Intended Use:

BMW's multi-lumen central venous catheters have the same intended use as Bard Access Systems' Groshong long-term central venous catheters, and Bard's Hickman preamendment long-term central venous catheters.

BMW's Clampless Valved Catheter-Tunneled is designed for patients who require long-term access to the central venous system for administration of fluids including, but not limited to, hydration fluids, antibiotics, chemotherapy, analgesics, nutritional therapy, 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 intravenous therapy.

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

BMW Medical, Inc. has developed a multi-lumen tunneled central venous catheter that provides the benefits of the valve incorporated at the distal tip of Bard's multilumen Groshong catheters on an open-ended catheter similar to Bard's Hickman multi-lumen central venous catheters. 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.

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BMW's Multi-lumen tunneled CVCs are trimmed from their distal ends whereas the Groshong legs may be trimmed from the proximal ends, necessitating final attachment of the Groshong catheters to their hubs by the user.

BMW's 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 Multi-lumen CVCs.

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 Multi-lumen CVC-Tunneled is at least as effective in minimizing these potentials as are the predicate devices. 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 Multi-lumen CVC-Tunneled is substantially equivalent to the predicate Hickman and Groshong multi-lumen central venous catheters manufactured by C. R. Bard.

Based on the above and physical comparisons, BMW's Multi-lumen Clampless Valved Catheter-Tunneled products were found to exhibit physical features and performance and safety characteristics which fall within the range of values typically found for Bard's open-ended Hickman catheters and valved Groshong catheters.

9. Conclusion

The BMW Clampless Valved Catheter-Tunneled products are substantially equivalent to Bard's valved Groshong and open-ended Hickman catheters.