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**BMW Medical Inc.'s Clampless Valved Catheter-PICC  
Premarket Notification**

**510 K SUMMARY  
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**3. Device Identification:**

Trade Name: Clampless Valved Catheter-PICC  
(CVC-PICC)  
Common Name: Peripherally Inserted Central Catheter (PICC)  
Classification Name: Long-Term Intravascular Catheter

**4. Predicate Device(s):**

Groshong Long-term PICC and HDC V-Cath® PICC.

**5. Device Description:**

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

BMW Medical, Inc.'s peripherally inserted central venous catheters are configured as long-term single lumen catheters. They 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 length and diameter to accommodate specific patient populations.

**BMW Medical Inc.'s Clampless Valved Catheter-PICC  
Premarket Notification**

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 proximal hub during aspiration of blood samples.

**6. Intended Use:**

BMW's CVC-PICC is designed to establish peripheral access to the central venous system for administration of fluids including, but not limited to, hydration agents, 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 peripherally inserted central venous catheter that provides the benefits of the valve incorporated at the distal tip of Groshong catheter on an open-ended PIC catheter similar to the V-Cath® 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 the central venous system and continuous direct blood contact that can potentially interfere with the function of valves continually exposed to blood flow. Additionally, BMW's CVC-PICC's are trimmed from the distal end, whereas the Groshong PICC's 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-PICC 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-PICC incorporates fixed suture wings (predicate devices have removable suture wings) and integral extension tubing. Because the extension

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Premarket Notification**

tubing is attached to the BMW CVC-PICC's, the priming volume of the BMW catheter is greater than that of the predicate devices.

BMW's catheter adapter (hub) is fabricated from a medical grade plastic that is not identical to that of the predicate devices. This material has been used for purposes identical to those intended for BMW's CVC-PICC in other products.

**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 BMW CVC-PIC 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 located in the CVC-PICC hub. 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 the 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-PICC is substantially equivalent to the predicate devices.

Based on the above and physical comparisons, the BMW CVC-PICC is substantially equivalent to the predicate devices, the Bard Groshong PICC, and HDC's V-Cath® PICC.

**9. Conclusion**

BMW's CVC-PIC catheters are substantially equivalent to Bard's Groshong PICC's and HDC Corp.'s V-Caths®.