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BMWMedical inc.
BROWN/MOOREHEAD/WILTA

510 K SUMMARY
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3. Device Identification:

Trade Name: Clampless Valved Catheter
Common Name: Central Venous Catheter
Classification Name: Long-term Intravascular Catheter

4. Predicate Device(s):

Hickman/Broviac catheters and Groshong valved catheters.

5. Device Description:

BMW Medical has developed a central venous catheter that provides the clampless valve features of the Groshong catheter on an open-ended Hickman catheter. The BMW valve is external to the central venous system and is protected inside an adapter attached to a Hickman-type catheter. 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 the Groshong three-way valve.

BMW Medical, Inc.'s 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, specific sizes designed for pediatric and adult populations.

A 2-piece plastic adapter is attached to the proximal end of each single lumen catheter. The catheter 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 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. The valve is captured (sandwiched) between the seating surfaces of the two-piece adapter. The seating surfaces of the adapter are held in position and bonded between the proximal (female luer) and distal (barbed) pieces.

In addition to central venous catheters, BMW intends to market a surgical tunneler which is used to form a subcutaneous tunnel from the catheter exit site, in the area just below the patient's nipple, to the entrance site near the patients mid-clavicular area.

6. Intended Use:

BMW's central venous catheters are designed for the administration of I.V. fluids, blood products, drugs, and parenteral nutrition solutions, as well as for blood withdrawal.

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

Physical characteristics of BMW long-term catheters, compared to Groshong and Hickman/Broviac catheters demonstrate that the physical characteristics of the BMW Catheters are identical to the Hickman /Broviac predicate device catheters for all items listed in the "FDA Guidance on Premarket Notification [(510(K)] Submission for Short-Term and Long-Term Intravascular Catheters." The only physical difference between the Hickman and Broviac catheters and similarly sized BMW Clampless Valved Catheters is that a three-way valve is located in the catheter adapter. Additionally, the priming of the BMW 2.7 F catheter is greater than that of the 2.7 F Broviac catheter owing to the greater size of the hub.

The only difference between the BMW tunneler and the Hickman/Broviac tunneler is that the BMW tunneler is shorter than the Hickman Broviac tunneler.

Physically, the BMW catheter differs from the Groshong catheter in that the valve is located in the catheter hub (BMW) instead of close to the distal tip (Groshong). Additionally, the Groshong catheters are supplied in shorter lengths. This length difference is only apparent when the catheters are removed from the package; in actual use, the catheters are trimmed to length so that their distal tips are located in the distal 1/3 of the superior vena cava (SVC). Thus, the difference in length of catheters, as supplied, is insignificant in relation to end-use of the product.

Both Hickman and BMW catheters are open-ended, and the distal end is trimmed in order to obtain the correct length. Because the Groshong catheter is close-ended

and removal of a distal segment would remove the valve, these catheters are trimmed at the proximal ends and subsequently fitted over their connectors. Placement and trimming of BMW's catheters, because they are open-ended, is identical to that of Hickman catheters.

BMW's three-way valve is located in the adapter at the proximal end of the catheter outside the patient's body while the Groshong three-way valve is located in the distal tip of the catheter in the distal third of the SVC,. There are no new safety or effectiveness issues posed by the external location of the BMW three-way valve or the shorter BMW subcutaneous tunneler.

Based on these physical characteristic comparisons, we consider the BMW Long-term Central Venous Catheters substantially equivalent to the Groshong and Hickman/Broviac predicate device catheters.

8. Assessment of Performance Data: Performance test results indicate BMW catheters are substantially equivalent to predicate device catheters for all performance characteristics itemized in the FDA Guidance on Premarket Notification [(510(K)] published April 16, 1996.

The BMW catheter performance characteristics related to valve function were compared to the Groshong predicate catheters. Comparison of all other BMW catheter performance characteristics were made to the range of values found for the performance of the predicate Hickman/Broviac as well as Groshong catheters. These comparisons indicate that the BMW catheters performed identically to, or better than the predicate devices for all performance characteristics studied.

Data indicate that BMW's valves exhibited superior performance in both the infusion and aspiration directions. In the infusion direction, they retain a greater column of water above them before opening, minimizing the potential for air embolism. In the aspiration direction, the valves effectively prevent bleedback, but negative aspiration pressures are not so great that they cause blood damage. These differences in valve function are a consequence of the design characteristics of the valves. The opening pressures in both direction are a function of the length of the slit in the silicone and the thickness of the silicone. In addition, the opening pressures of the BMW valve are dependent on the dimensions of the valve seat. The difference in performance between the two valves is most affected by the seat configuration. The rigid support of the adapter of the BMW valve is more readily controlled than the flexible, curved surface of the silicone rubber catheter adjacent to the slit in the Groshong catheter, permitting greater control over valve function.

9. No Clinical Evaluations were used to justify Performance of device.

10. Conclusion: Data indicate that the performance characteristics of the BMW valved catheters are superior to the Groshong catheters while not posing any new safety or efficacy issues.