

K961225

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510(k) Premarket Notification  
Modified Solution Administration Sets

**510(k) SUMMARY**

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**Proposed Device:**

Modified Baxter Solution Administration Sets

**Predicate Devices:**

Current Baxter Solution Administration Sets

**Proposed Device Description:**

Baxter Healthcare Corporation intends to manufacture and market solution administration sets with an alternate design of the spike and drip chamber components.

**Summary of Technological Characteristics of New Device to Predicate Devices**

The proposed Baxter sets are the same as existing Baxter sets except for the design change in the spike and drip chamber components. All other components of the solution administration sets remain unchanged. The proposed spike and drip chamber components are identical in material composition and function to existing components. The spike remains the same in all container interfacing dimensions. Thus the proposed sets will continue to be compatible with both Baxter and competitive solution containers as was established in K860272 for the current spike design. Also the geometry of the drop former and portion of the spike which engages the drip chamber is the same as the current design.

**Discussion of Nonclinical Tests; Conclusions Drawn from Nonclinical Tests**

Data regarding the functional performance of the proposed spike and drip chamber assemblies have been generated including air passage, air leakage and tensile strength tests. Performance testing indicates that sets with the proposed components will meet or exceed all functional requirements.