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**510(k) SUMMARY**  
**Stopcock Manifold Gangs**

**Submitted by:**

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**Proposed Device:**

Baxter Stopcock Manifold Gangs

**Predicate Devices:**

Medex, Inc. Ultra® Stopcock  
Medex, Inc. Stopcock Manifold Gangs  
Baxter Stopcock Manifold Gangs

**Proposed Device Description:**

Stopcock manifold gangs consist of individual stopcocks assembled in series through common luer fittings to form a manifold or stopcock gang. These pre-assembled stopcock gangs provide multiple access sites into a common fluid path for the administration of drugs and solutions. The luer connectors on either end of the stopcock gang allow connection to an IV set for fluid administration through an indwelling intravascular catheter.

Baxter will purchase stopcocks from Medex, Inc. and will assemble individual stopcocks into ganged configurations containing 2, 3 or 5 stopcock units. Baxter will use Medex stopcocks which vary in the number of flow paths (3 or 4 way), internal lumen diameter (large bore or standard bore) and type of luer connection (male luer slip, rotating male luer lock, and female luer lock) may be used to produce the gangs. The stopcock manifold gangs may also be marketed with a pre-attached backing plate which can be used to attach the stopcock gang to an IV pole.

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

The proposed Baxter stopcock manifold gangs will consist of multiple Medex stopcocks preassembled with Baxter port protectors and backing plate. These stopcocks are currently manufactured and marketed as single unit products only. The differences from currently marketed Medex stopcocks include assembly into multiple unit gangs, and the addition of Baxter port protectors and backing plate. There are no other changes in the design, components, materials, function or intended use of the Medex stopcocks.

In addition, Medex markets stopcock manifold gangs consisting of multiple stopcocks of a different type but with the same configurations as the proposed Baxter products e.g. 2, 3 and 5 unit gangs consisting of 3 or 4 way and large or standard bore stopcocks with varying luer type connections.

There are no new materials involved in the proposed products. Solution-contacting materials to be used in Baxter's proposed stopcock manifold gangs have been previously used in marketed Medex stopcocks or in other Baxter devices for similar IV solution administration applications.

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

Data regarding the functional performance of the proposed stopcock manifold gangs has been generated. Testing includes pressure seal tests, stopcock luer conformance to ANSI standard MD70.1-1983, lipid compatibility, luer to luer stability, flow rate and mechanical security of stopcock gang to backing plate. Performance testing indicates that the proposed products meet or exceed all functional requirements and support their suitability for use.