

K960787

510(k) Premarket Notification  
Irrigation Sets

**510(k) SUMMARY**  
Irrigation Sets

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**Proposed Device:**

Irrigation Sets with Modified Tubing Segment

**Predicate Devices:**

Current Baxter Irrigation Sets

**Proposed Device Description:**

Baxter's line of irrigation sets are intended for delivery of irrigating solutions from the fluid container to the irrigation site during bladder irrigation or endoscopic procedures including cystoscopy, transurethral resection (TUR) and arthroscopic procedures. The subject of this submission is a material change in the distal tubing segment of the irrigation set from natural rubber latex to styrene ethylene butadiene styrene (SEBS). This tubing segment is connected to the endoscope for delivery of solution to the irrigation site such as the bladder or knee joint. The change from latex to SEBS is being made to improve user safety by eliminating the potential for sensitivity reactions associated with natural rubber proteins.

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

The proposed irrigation sets are identical to current Baxter irrigation sets except for the material change from latex to SEBS in the tubing segment. The design and dimensions of the latex tubing segment will remain unchanged. Also, all other materials of the irrigation sets, as well as overall product design and intended use will remain unchanged.

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

The biological and chemical reactivity of the new SEBS material has been assessed using biological methods specified in ISO Standard 10993-1 and USP Physicochemical tests. The material was found to be acceptable for its intended use.

Data regarding the functional performance of irrigation sets with the proposed SEBS tubing segment have been generated. Studies included kink testing, pull testing and pressure testing. Performance testing indicate that the proposed irrigation set meets or exceeds all functional requirements and support its suitability for use.