K961446

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I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

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Device

Trade Name:	AQ Hydrophilic Stent
Proposed Classification Name:	Splint, Ureteral

Predicate Devices:

The AQ Hydrophilic Stent is substantially equivalent to predicate devices in terms of indications for use, design, and materials of construction. Predicate devices include the Slipcoat™ Stent manufactured by Cook Urological, the Hydro-Plus™ manufactured by Microvasive and the Lubri-Flex™ Ureteral Stent, K905289, manufactured by Surgitek®.

Device Description:

The AQ Hydrophilic Stent is used for temporary internal drainage from the ureteropelvic junction to the bladder. The hydrophilic coating will allow the stent to become 'slippery-when-wet' which will reduce friction. This device will be made from polyurethane, silicone and a hydrophilic coating.

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Substantial Equivalence:

The device will be manufactured according to specified process controls and a Quality Assurance Program. The device will undergo packaging and sterilization procedures similar to devices currently marketed and distributed by Cook Urological. Being similar with respect to indications for use, materials and physical construction to predicate devices, this device meets the requirements for section 510(k) substantial equivalence.