

J. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

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Device:

Trade Name: LSe Stent Sets

Proposed Classification Name: Splint, Ureteral 78 FAD

Predicate Devices:

The LSe Stent Sets are substantially equivalent to predicate ureteral stents in terms of indications for use, design, construction and materials equivalence. Predicate devices include:

- Cook Urological® Ureteral and Urethral Stents manufactured by Cook Urological®. Cook Urological® Ureteral and Urethral Stents are preamendment.
- Cook Urological® EchoSight® Sof-Flex® Stents manufactured by Cook Urological®.
- Cook Urological® SlipCoat™ Stents manufactured by Cook Urological®.

Device Description:

The LSe Stent Sets are used for temporary internal drainage from the ureteropelvic junction to the bladder. The stents have been Ion Implantation treated for reduced surface friction and enhanced surface energy. The materials used in these devices are stainless steel, TFE, polypropylene, polyurethane, silicone and vinyl. Stainless steel and TFE are widely used in the medical field and biocompatibility is assured. Biocompatibility testing has been performed on the polyurethane, silicone and vinyl and results show the materials to meet the requirements of these tests. The polypropylene does not come into contact with body tissue.

Substantial Equivalence:

This device will be manufactured according to specified process controls and a Quality Assurance Program. These devices will undergo packaging similar to the devices currently marketed and distributed by Cook Urological®. When marketed as sterile, these devices will undergo sterilization similar to the 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.