

510(k) Premarket Notification
Circle Nephrostomy Catheter Set
Cook Urological, Incorporated

J. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

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Device:

Trade Name: Circle Nephrostomy Catheter Set

Proposed Classification Name: Catheter, Nephrostomy, General & Plastic Surgery 79 GBO

Predicate Devices:

The Circle Nephrostomy Catheter Set is substantially equivalent to predicate circle nephrostomy catheter sets in terms of indications for use, design, construction and materials equivalence. Predicate devices include:

- Silastic[®] U-Tube Nephrostomy Kit manufactured by Dow Corning Corporation.
- Circle Nephrostomy Tube manufactured by Mentor Urology

Device Description:

The Circle Nephrostomy Catheter Set is used for temporary or permanent urinary diversion following nephrostomy, nephroureterostomy or other stenotic or obstructed UPJ procedures. The materials used in this device are silicone, polyvinylchloride and polypropylene. Biocompatibility testing has been performed on the silicone. Results show the material to meet the requirements of these tests. The polyvinylchloride and polypropylene do not come into contact with body tissue.

Substantial Equivalence:

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