

510(k) Premarket Notification
Laser Fiber Delivery/Cleaning Catheter
Cook Urological, Incorporated

K960768

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

MAY 14 1996

Submitted By:

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1100 West Morgan Street
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Device:

Trade Name: Laser Fiber Delivery/Cleaning Catheter

Proposed Classification Name: Endoscope and/or Accessories 78 KOG

Predicate Devices:

The Laser Fiber Delivery/Cleaning Catheter is substantially equivalent to predicate laser fiber delivery and laser fiber delivery/cleaning catheters in terms of indications for use, design, construction and materials equivalence. Predicate devices include:

- Lasercath™ manufactured by HGM Medical Laser Systems, Inc.
- Continuous Flow Laser Cystoscope manufactured by CIRCON ACMI.
- Laser Fiber Insert manufactured by Cabot Medical.

Device Description:

The Laser Fiber Delivery/Cleaning Catheter is used to protect the delivery of a laser ablation fiber, for periodic, intraoperative cleaning of charred, thermally degraded tissue from the laser fiber and for irrigation of the surgical site. The 5.7Fr Laser Fiber Delivery/Cleaning Catheter will accept laser fibers up to 1250 microns (0.050 inch). The 8.0Fr Laser Fiber Delivery/Cleaning Catheter will accept laser fibers up to 1500 microns (0.060 inch). The materials used in this device are polyethylene, nylon, acetal, polyvinylchloride and polycarbonate. Biocompatibility testing has been performed on the polyethylene and results show the materials to meet the requirements of these tests. The nylon, acetal, polyvinylchloride and polycarbonate 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.