OCT 18 1996

K961904

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

Tammy Bacon
Cook Urological
1100 West Morgan Street
Spencer, Indiana 47460
(812) 829-4891
May 15, 1996

Device

Trade Name:	AQ Hydrophilic Dilators
Proposed Classification Name:	Dilator, Catheter, Ureteral Dilator, Urethral

Predicate Devices:

The AQ Hydrophilic Dilators are substantially equivalent to predicate devices in terms of indications for use, design, and materials of construction. Predicate devices include the Ureteral Dilators with Hydro Plus™ manufactured by Microvasive and uncoated dilators manufactured by Cook Urological.

Device Description:

The AQ Hydrophilic Dilators are intended to dilate the suprapubic and/or nephrostomy fascial tract, urethra and ureters. The constructions of the materials are polyurethane, polyethylene and vinyl. The hydrophilic coating will allow the catheters to become lubricious which will reduce friction.

Substantial Equivalence:

These devices 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, these devices meet the requirements for section 510(k) substantial equivalence.