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510(k) Premarket Notification
AQ Hydrophilic Catheters
Cook Urological

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:

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1100 West Morgan Street
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Device

Trade Name: AQ Hydrophilic Urological Catheters

Proposed Classification Name: Catheter, Urological
Catheter, Ureteral, Gastro-Urology

Predicate Devices:

The AQ Hydrophilic Urological Catheters are substantially equivalent to predicate devices in terms of indications for use, design, and materials of construction. Predicate devices include the Slip-Coat™ Catheters manufactured by Cook Incorporated and uncoated urological catheters manufactured by Cook Urological.

Device Description:

The AQ Hydrophilic Urological Catheters are intended for drainage, irrigation and/or retrograde pyelogram. Materials that comprise these devices are polurethane, polyethylene, vinyl and hydrophilic coating. 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. These devices 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.