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**510(k) Premarket Notification
Ascend™ Balloon Dilation Catheter
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: Ascend™ Balloon Dilation Catheter
Proposed Classification Name: Dilator, Catheter, Ureteral

Predicate Devices:

The Ascend™ Balloon Dilation Catheter is substantially equivalent to predicate devices in terms of indications for use and design. Predicate devices include Balloon Dilation Catheters manufactured by Bard and High Pressure Ureteral Dilatation Balloon Catheter manufactured by Microvasive.

Device Description:

The Ascend™ Balloon Dilation Catheter is used for ureteral dilation prior to ureteral stone manipulation or ureteroscopy, and dilating the intramural ureter. The materials used to construct the balloon are urethane and polyethylene. The Ascend™ Balloon Dilation Catheter will be offered in a 7 FR diameter and 40cm to 65cm long catheter with a 5mm to 10mm x 4cm to 12cm balloon.

Substantial Equivalence:

The device 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, this device meets the requirements for section 510(k) substantial equivalence.