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EXHIBIT #7

510(k) Summary

Kendall Curity® Ureteral Catheter

In accordance with section 513(i) of the SMDA and as defined in 21 CFR Part 807.3 final rule dated December 14, 1994, this summary is submitted by:

Kendall Healthcare Products Company
15 Hampshire Street
Mansfield, MA 02048
Date: November 25, 1996

1. Contact Person

David A. Olson
Manager Regulatory Affairs
(508) 261-8530

2. Name of Medical Device

Classification Name:	Gastro-Urology Ureteral Catheter
Common or Usual Name:	Ureteral Catheter
Proprietary Name:	Curity Ureteral Catheter

3. Identification of Legally Marketed Device

The proposed Kendall Curity Ureteral Catheter is substantially equivalent in intended use, design and function to the commercially available Bard Ureteral Catheter (Pre-Amendment Device); Cook Ureteral Catheter, 510(k) No. K923729.

4. Device Description

The proposed Kendall Curity Ureteral Catheter is a sterile, single use device which facilitates preliminary procedural components of ureteroscopy. The catheter is a single lumen extrusion fabricated from nylon resin. Graduated placement markers on the catheter shaft will allow the urologist to determine the extent of catheter advancement. The proximal end of the catheter has a friction fitted luer lock adapter. The distal catheter tip will be manufactured in a cone tip, open tip or whistle tip configuration. The catheter will be sold in a standard 70 cm working length in French sizes ranging from 4.0 Fr. to 7.0 Fr.

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5. Device Intended Use

The Kendall Curity Ureteral Catheter is intended to be used to inject contrast medium for fluoroscopic ureteral visualization, to direct a guidewire into the ureter and for urinary drainage.

6. Product Comparison

The Kendall Curity Ureteral Catheter is equivalent to the referenced predicate devices in that they are fabricated from similar materials have the same function, equivalent indications for use, and similar designs.

7. Nonclinical Testing

Biocompatibility testing was performed on the catheter following ISO-10993 Biological Evaluation of Medical Devices. This testing found the material contained no toxic diffusible substances.

Functional/Mechanical testing was performed to determine flow rates, shaft kink, shaft stiffness, shaft tensile, cone tip/shaft bond and shaft radiopacity. Testing showed equivalence between the proposed catheter and referenced predicate devices.