K970969

APR 23 1997

Exhibit 6

510(k) Summary

Kendall CURITY Suprapubic Catheter Trays and Kits

In accordance with section 513(I) of the SMDA and as described 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: February 6, 1997

1. Contact Person

David A. Olson, Regulatory Affairs
Telephone: (508) 261-8530

2. Name of the Device

Classification Name:	Suprapubic Urological Catheter and Accessories
Common or Usual Name:	Suprapubic Catheter
Proprietary Name:	Kendall CURITY Suprapubic Catheter Trays and Kits

3. Statement of Substantial Equivalence

The Kendall CURITY Suprapubic Catheter Trays and Kits are substantially equivalent in intended use, design and function to the Kendall CURITY Suprapubic Drainage System, 510(k) No. K842899.

4. Description of Device

The Kendall Suprapubic Catheter Trays and Kits are sterile, single use devices which are designed to provide suprapubic access to the bladder for bladder irrigation and urine drainage. The proposed device consists of 100% silicone suprapubic catheters in 10, 12 and 14 French sizes packaged with various accessories.

The catheters are two-way balloon catheters having a drainage and inflation lumen.

K970969
2 of 2

5. Device Intended Use

The Kendall CURITY Suprapubic Catheter Trays and kits are intended to provide urinary bladder drainage or irrigation by percutaneous placement of a suprapubic catheter. This is a useful method of controlling urinary bladder drainage postoperatively.

6. Product Comparison

The Kendall CURITY Suprapubic Catheter Trays and Kits is equivalent to the referenced predicate device 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, balloon burst volume, valve retention, funnel/shaft bond strength, static load, dynamic load, water loss and non-deflator test. Testing showed equivalence between the proposed catheter and commercially available suprapubic catheters.