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**510(k) SUMMARY**

**Submitter:** A+ Medical Products, Inc.  
16 Alden Place  
Newton, MA 02165  
(617) 964-7412

**Contact Person:** Linda R. Asta, President

**Device Name:** Asta-Cath™ Guide  
Female Self Catheter Guide

**Classification Name:** Urinary Catheter Accessory

**Legally Marketed Equivalent Device:** Autocath Set, 510(k) number K910876

**DESCRIPTION OF DEVICE**

The Asta-Cath™ is a female catheter guide designed to teach and/or assist women or their caretakers in performing self-catheterization. The Device consists of a handle which has three alignment holes and a vaginal insert. It is made of the Perspex® GHF Acrylic Polymer CP-927 GHF.

The Asta-Cath™ guide inserts into the vagina and spreads the labia to allow for easy access of a catheter into the urethra. When the Asta-Cath™ guide is in place, one of the three alignment holes will align with the urinary meatus, thus allowing easy access of a catheter into the urethra.

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**510(k) SUMMARY (Cont.)**

**INDICATIONS FOR USE**

The Asta-Cath™ female catheter guide is intended for use in the following situations:

- (i) As an assistive device for women who have difficulty performing intermittent self catheterization due to motor or visual disabilities;
- (ii) As a teaching aide for women learning to catheterize themselves for the first time;
- (iii) As a teaching aide for caregivers who will be catheterizing women;
- (iv) As an assistive device and teaching aide for women who are required to perform intermittent self catheterization temporarily following surgery.

**TECHNOLOGICAL INFORMATION**

The Asta-Cath™ female catheter guide is substantially equivalent to the Autocath Set, 510(k) number K910876. The indications for use for the Asta-Cath™ guide and the Autocath Set are identical. The technological characteristics and performance of the Autocath device are substantially similar to those of the Asta-Cath™ guide. The placement of the alignment holes on the Asta-Cath™ guide differ from that of the Autocath device in that the holes are located on the handle portion of the device rather than the vaginal insert portion. This minor technological difference improves the effectiveness of the Asta-Cath™ guide and does not interfere with its safety and performance.