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ITEM 8: 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

The purpose of this 510(k) Premarket Notification is to request clearance to market ProSys™ SAMEC™ LA under the ConvaTec ProSys™ product line of incontinence products.

ProSys™ SAMEC™ LA is intended for use in the management of male urinary incontinence. This device is not significantly different from other one-piece self-adhering male external catheters used in the management of male urinary incontinence. ProSys™ SAMEC™ LA is substantially equivalent to Mentor Urology, Inc.'s Freedom Cath® Self-Adhering Male External Catheter. The indications and contraindications for ProSys™ SAMEC™ LA are substantially equivalent to Freedom Cath® and other latex self-adhering male external catheters.

Biocompatibility testing demonstrated that the adhesive material used in ProSys™ SAMEC™ LA is safe for human use. The adhesive material is non-toxic, non-sensitizing and resulted in a Primary Irritation Index of 0.25, where an index between 0 and 2 is classified as mildly irritating. Typically, any material which results in a Primary Irritation Index of 2 or less can be considered to have passed the Skin Irritation Test. In this case, the Primary Irritation Index of 0.25 is well within the range of acceptable values.

Biocompatibility testing demonstrated that the latex rubber is non-toxic, non-irritating, and non-sensitizing. The latex rubber did not pass Cytotoxicity (Agar Overlay or MEM Elution) testing. These test results are expected due to the fact that latex rubber is the positive control for these tests. According to USP guidelines, dilutions may be performed to determine a material's endpoint if it fails the MEM Elution test initially. The MEM Elution was repeated with a dilution of 1:32 latex rubber and passed.

The results of all testing are provided in Item 5.

Based upon the above information, ProSys™ SAMEC™ LA is substantially equivalent to Freedom Cath®.