

K963950



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**EXHIBIT 10.1: BioDerm® EID® MALE EXTERNAL INCONTINENCE
DEVICE**

510(k) SUMMARY

Submitted by:
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Device Name: BioDerm® EID® MALE EXTERNAL INCONTINENCE DEVICE

- (a) Indications for Use
The BioDerm® EID® is an external male catheter intended for the management of urinary incontinence in males. It facilitates urine drainage into a urine collection bag.
- (b) Biocompatibility
The results of the biocompatibility tests show the device to be safe for its intended purpose.
- (c) Substantial Equivalence
The BioDerm® EID® male external catheter is substantially equivalent to the Hollister PolyTech™, non-latex, self-adhesive urinary external catheter predicate device.