

Bard Urological Division
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SECTION VI

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

A. Submitter's Information:

Submitter's Name: C. R. Bard, Inc.
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Date of Preparation: January 9, 1997

B. Device Name:

Trade Name: Bard® Flexible Endoscopy Injection System

Common/Usual Name: Flexible Endoscopy Injection System

Classification Name: Endoscope and Accessories, Class II

C. Predicate Device Names:

Trade Name: Bard® Endoscopic Injection System

D. Device Description:

The Bard® Flexible Endoscopy Injection System consists of an endoscopic injection needle with an endoscopic working channel protector, a stainless steel endoscopic stabilizer sheath and optional medical tape for affixation purposes.

E. Intended Use:

The Bard® Flexible Endoscopy Injection System is indicated as an accessory for currently available endoscopes to provide for delivery of injectable materials into tissues in the urinary bladder and lower urinary tract via percutaneous access through a pre-placed 20 Fr. (minimum) introducer. The system is designed for use with flexible endoscopes no larger than 18 Fr. and having a working channel accommodating 5 Fr. instrumentation.

F. Technological Characteristics Summary:

Table VI-A provides a tabular comparison of the technological characteristics of the Bard® Flexible Endoscopy Injection System versus the predicate device.

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TABLE VI-A: COMPARISON CHART TO PREDICATE DEVICE

Device Feature	Bard® Flexible Endoscopy Injection System	#K933815 Bard® Endoscopic Injection System (Predicate Device)
Injection Needle Luer Lock Hub	USP Class VI Polymer*	USP Class VI Polymer
Injection Needle Strain Relief	USP Class VI Polymer*	USP Class VI Polymer
Injection Needle Catheter Shaft	5 Fr., 26" USP Class VI Polymer	5 Fr., 13.14" USP Class VI Polymer
Injection Needle	23 Gauge 0.25" Stainless Steel (304 grade) Non-Coring Needle	23 Gauge 0.5" Stainless Steel (304 grade) Non-Coring Needle
Endoscopic Stabilizer	304 Stainless Steel Tube fitting over an 18 Fr. (max.) flexible endoscope and through a preplaced 20 Fr. percutaneous introducer	USP Class VI Polymer tube with positive stop fitting <u>inside</u> endoscopes accommodating 7 Fr. instrumentation
Stabilizer Affixation	Medical tape for securing stabilizer sheath to flexible endoscope shaft	Working channel cap fitting over positive stop of stabilizer
Endoscopic Working Channel Protector	USP Class VI Polymer tube used as a protective sheath for insertion of the injection needle	None

* Materials and dimensions identical to predicate device.