

MAY 28 1996

0000062

Bard Urological Division
 C. R. Bard, Inc.
 8195 Industrial Blvd.
 Covington, GA 30209-2695



510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

A. Submitter's Information:

Submitter's Name: C. R. Bard, Inc., Urological Division
 Address: 8195 Industrial Boulevard
 Covington, Georgia 30209
 Phone: 770-784-6135
 Fax: 770-784-6419
 Contact Person: Donna J. Wilson
 Date of Preparation: March 29, 1996

B. Device Names:

Trade Names: Bard® Platinum Class™ 3 French Flat Wire Stone Basket
 Bard® Platinum Class™ 3 French High-Torque Helical Stone Basket
 Bard® Platinum Class™ 3 French Grasping Forceps
 Common Name: Ureteral Stone Dislodger
 Classification Names: Dislodger, stone, basket, ureteral, metal
 [Flat Wire Stone Basket, Helical Stone Basket, Grasping Forceps]

C. Predicate Device Names:

Trade Names: Bard® Platinum Class™ 3 French Flat Wire Stone Basket
 Bard® Platinum Class™ 3 French High-Torque Helical Stone Basket
 Bard® Platinum Class™ 3 French Grasping Forceps

D. Device Description:

The Bard® Platinum Class™ 3 French Ureteroscopic Instrument product line consists of three separate instruments or stone dislodgers: the Flat Wire Stone Basket, the High-Torque Helical Stone Basket, and the Grasping Forceps. These instruments are each constructed of three main assemblies: a handle assembly, shaft assembly, and stone capture mechanism consisting of an expandable basket or grasping forceps assembly. Stone dislodgers (baskets or grasping forceps) may be used in the removal of renal and ureteral stones and calculi by inserting the stone basket or grasping forceps (while in a closed position) through the working channel of an endoscope and into the ureter or renal pelvis. The tip of the basket or forceps is advanced past the stone

and the expandable basket or forceps is opened, manipulated and closed around the stone, thereby capturing it for removal. Once the stone has been captured, the basket or forceps should be partially closed to keep the stone from dislodging while the device and endoscope are being withdrawn.

The devices have a 3 Fr. outer diameter shaft size and each is available in three different lengths, 70cm, 90cm and 115cm.

E. Intended Use:

Bard® Platinum Class™ Ureteroscopic 3 French Flat Wire Stone Basket is indicated for use in the endoscopic removal of renal and ureteral stones and calculi.

Bard® Platinum Class™ Ureteroscopic 3 French High-Torque Helical Stone Basket is indicated for use in the endoscopic removal of renal and ureteral stones and calculi.

Bard® Platinum Class™ Ureteroscopic 3 French Grasping Forceps is indicated for use in the endoscopic removal of renal and ureteral stones and calculi.

F. Technical Characteristics:

The **Bard® Platinum Class™ 3 French Ureteroscopic Instruments** are constructed of biocompatible materials. Most of the materials used in the construction are typical for similar accessories. These include thermoplastics, 300 or 400 series stainless steel, solder, nickel titanium, fluoropolymers, polyimide, cyanoacrylate and epoxy.