



OCT 21 1996

K962611

12. SUMMARY OF SAFETY AND EFFECTIVENESS

Date of Preparation: June 28, 1996

Device Name: Ryder Urological Balloon Catheter Inflation Device

Classification Name: Balloon Inflation/Deflation Device

Manufacturer: Ryder International Corporation, PO Box 564, 1426 Curt Francis Road, Arab, AL 35016

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Predicate: Ryder International Balloon Catheter (USCI® Ideal™) Inflation Device cleared for market under K953522.

**Device Description/
Intended Use:**

The Ryder Urological Balloon Catheter Inflation Device consists of a plastic syringe with a screw-type plunger and a locking lever and rotating palm grip that control the plunger, a manometer to measure pressure and a high pressure connecting tube.

The Device has a fluid capacity of 20 cc and an operating pressure range of vacuum to 20 atm.

The inflation device is intended for single use while performing urological balloon dilation procedures to inflate the balloon, monitor the pressure within the balloon and deflate the balloon.

Technological Characteristics:

The Ryder Urological Balloon Catheter Inflation Device has an operating pressure range of vacuum to 20 atm while the predicate device has a range of vacuum to 30 bars. There are no other significant technological characteristics that distinguish the two devices, and no differences that should pose a risk to patient safety.

Summary of Safety Testing:

The materials of the device which contact the contrast solution in use have been tested using USP guidelines and the results of these studies indicate that the product is safe for its intended use.