

JUL 18 1996

K962604

**510(k) Premarket Notification**  
ProSys™ Custom Fit Leg Bag with Preattached  
Adjustable Inlet Tube for Patient Sizing

**ITEM 8: 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

The purpose of this 510(k) Premarket Notification is to request clearance to market ProSys™ Custom Fit Leg Bag with Preattached Adjustable Inlet Tube for Patient Sizing which is available in a volume capacity of 500ml. Each non-sterile bag is fitted with a permanently welded adjustable inlet tube with a self-packaged connector which connects to an external catheter. The inlet tube is available in one (1) size, 600mm to accommodate patient preference. Fabric straps are used to secure the leg bag in place. The leg bag has a T-tap drainage valve. The inlet tube contains an anti-reflux valve to reduce the risk of urine backflow and infection and a sample port used for urine sampling is integrated into the universal connector.

ProSys™ Custom Fit Leg Bag with Preattached Adjustable Inlet Tube for Patient Sizing is substantially equivalent to ProSys™ Leg Bag (Non-Sterile). Both devices are indicated for the management of urinary incontinence. Both devices function in the same manner: they collect and contain urine. Both systems are reusable.

The components of ProSys™ Custom Fit Leg Bag with Preattached Adjustable Inlet Tube for Patient Sizing have been subjected to extensive biocompatibility testing with results which demonstrate that the components are acceptable for use. One cytotoxic result was noted for the fabric leg bag straps and this result is further explained in Item 5b. All other testing indicates that the components are non-irritating or negligibly irritating, non-sensitizing and non-cytotoxic.

Bench testing performed on ProSys™ Custom Fit Leg Bag with Preattached Adjustable Inlet Tube for Patient Sizing included tests for connector strength of attachment, resistance to bursting, resistance to impact, and for leakage. Additionally, the anti-reflux valve was also tested. All components performed at an acceptable level and the test results appear in Item 5a.

A comparison of the indications for use, the components, functions and characteristics of ProSys™ Custom Fit Leg Bag with Preattached Adjustable Inlet Tube for Patient Sizing and the ProSys™ Leg Bag (Non-Sterile) indicates that these products are substantially equivalent