

**SUMMARY OF SAFETY AND EFFECTIVENESS**

K960004

**MEDICAL DEVICE TECHNOLOGIES, INC.**

**CELL RECOVERY SYSTEM™ (CRS) 510(k)**

MAR 20 1996

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**Date 510(k) Prepared:** December 28, 1995

**Device Name:** Cell Recovery System™

**Classification Name:** Endoscope and Accessories

**Classification:** Class II

The MDT Cell Recovery System™ (CRS) is an automated cytology brush for use with a rigid or flexible cystoscope in the collection and retrieval cells for cytological evaluation. The brush, consisting of nylon bristles secured by twisted stainless steel wires fused and blunted at the tip, is attached to a nickel-titanium shaft and housed in a Teflon sheath. The brush and sheath are designed for single use with cystoscopes having a 6 French working channel. The brush diameter is 10 mm, the brush length is 6.4 mm, and the sheath is 156 cm long. This cytology brush is similar in size, features and components to other commercially available cytology brushes and has the same intended use.

The CRS facilitates brushing of cells by automating the rotation of the cytology brush and aspiration of dislodged cells using a battery operated console coupled to the brush. The console is operated using either hand switches or a foot pedal for hands free operation. By pre-selecting the rotation speed between 0-300 rpm the operator can maneuver the brush to the desired location and initiate the brushing procedure as well as the sample retrieval into a syringe using the foot pedal.

Results from non-clinical studies including bench top testing, in-vivo studies in pig bladders and biocompatibility testing with the CRS to as well as clinical studies with a similar prototype have also shown automated brushing to be safe and effective. These studies have demonstrated that the automated features do not pose new safety questions when compared to currently marketed manual cytology brushes.

The CRS is substantially equivalent to a variety of currently marketed cytology brushes by various manufacturers including Surgitek, Teleded, Microvasive, Wilson-Cook, Wiltek, Hobbs, Mill-Rose, and Cook Urological.