

K965037

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**SUMMARY OF SAFETY AND EFFECTIVENESS**

**MEDICAL DEVICE TECHNOLOGIES, INC.**

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

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Date 510(k) Prepared: December 16, 1996

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 of 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, including the previous CRS version, 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 a foot pedal for hands free operation. The operator can maneuver the brush to the desired location and initiate the brushing procedure as well as the sample retrieval into a 60 cc syringe.

Results from bench-top testing showed the modified CRS is substantially equivalent to the previous version of the CRS device cleared for marketing on March 20, 1996. These studies have demonstrated that the modified CRS features do not pose new safety questions when compared to the currently marketed CRS device.