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**APPENDIX VIII**

**510(k) SUMMARY**

**510(k) NUMBER:** PENDING

**SUBMITTED BY:** Applied Medical Resources Corporation  
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**DATE OF PREPARATION:** June 19, 1996

**NAME OF DEVICE:** Applied Medical Specimen Retrieval Bag

**CLASSIFICATION NAME:** Organ bag

**TRADE NAME:** Not Determined

**SUMMARY STATEMENT:** The Applied Medical Specimen Retrieval Bag is substantially equivalent to the predicate device (Endopouch™ Specimen Retrieval Bag) manufactured by Ethicon. The Specimen Retrieval Bag is indicated for use as a receptacle for the collection and extraction of tissue, organs and calculi during general and laparoscopic surgical procedures. The Applied Medical Specimen Retrieval Bag consists of a stylet, an introducer sheath with a locking pneumoperitoneal seal at the proximal end and a retrieval bag sealed radially on the distal end. The locking seal serves as a mechanism for maintaining positive pressure in the peritoneal cavity during laparoscopic procedures. The sheath contains a dual lumen, where the larger of the two lumens acts as the working channel for the insertion and removal of grasping instruments while the second and smaller lumen contains the bag activation wire for positioning, opening and closing of the bag. The dual lumen design allows the use of a single trocar for placement and retrieval of tissue, organs and calculi. Mechanical and biocompatibility tests were performed to verify functional and structural integrity and material safety. All testing demonstrated the Applied Medical Specimen Retrieval Bag is comparable to the predicate devices and introduces no new safety and effectiveness issues when used as indicated.