

K963359

APPENDIX VII

SEP 24 1996

510(k) SUMMARY

510(k) NUMBER: PENDING

SUBMITTED BY: Applied Medical Resources Corporation
26051 Merit Circle, Unit# 103
Laguna Hills, California 92653
(714) 582-6120 EXT. 310

CONTACT PERSON: Howard V. Rowe

DATE OF PREPARATION: August 21, 1996

NAME OF DEVICE: Applied Medical Insufflation Needle.

CLASSIFICATION NAME: Endoscope Accessories.

TRADE NAME: Not Determined

SUMMARY STATEMENT: The AMR Insufflation Needle is a disposable device indicated for use for insufflating the peritoneum prior to laparoscopic surgery. The design consists of a 14 gauge stainless steel needle attached to a plastic handle. The Insufflation Needle features a spring loaded safety stylet. The position of the safety stylet may be determined external to the patient by a color coded indicator on the handle. The needle will be made in two lengths, 120 and 150mm and contains a stopcock with a luer port for connection to an insufflation pump.

The Applied Medical Insufflation Needle has the same use methodology, design and indications as the predicate devices. Mechanical testing was conducted to verify the safety and functional performance of the AMR Insufflation Needle. All testing demonstrated the Applied Medical Insufflation Needle is comparable to the predicate devices and introduces no new safety and effectiveness issues when used as indicated.