

K971498

APPENDIX VIII

510(k) SUMMARY **MAY -5 1997**

510(k) NUMBER: PENDING

SUBMITTED BY: Applied Medical Resources Corporation
26051 Merit Circle, Unit# 103
Laguna Hills, California 92653
(71) 582-6120

CONTACT PERSON: Howard V. Rowe

DATE OF PREPARATION: April 22, 1997

NAME OF DEVICE: Applied Medical Laparoscopic Guidewire

CLASSIFICATION NAME: Urological Catheter and Accessories, 21CFR
876.5130.

TRADE NAME: Not Determined

SUMMARY STATEMENT:

The Applied Medical Laparoscopic Guidewire is intended to assist the physician in navigation, placement and exchange of laparoscopic and general surgical instrumentation. The Applied Medical Laparoscopic Guidewire is substantially equivalent in function, physical configuration and materials to the Applied Medical Urological Guidewire approved under K944135/A and a guidewire marketed by Cook Urological under K880100. The Applied Medical Laparoscopic guidewire and the predicate devices have a radiopaque body with a flexible, tapered tip allowing ease of access and visibility during placement. Differences include a change of indicated use and a selection of different lengths.

Mechanical and biocompatibility tests were performed to verify functional and structural integrity and material safety. All testing has demonstrated that the Applied Medical Laparoscopic Guidewire is comparable to the predicate device and introduces no new safety and effectiveness issues when used as indicated.