

K963886
April 24, 1997

APPENDIX IX

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: September 21, 1996

NAME OF DEVICE: Applied Medical Expanding Vascular Sheath.

CLASSIFICATION NAME: Catheter introducer

TRADE NAME: Expanding Vascular Sheath

SUMMARY STATEMENT:

The Applied Medical EVS is a single-use sheath intended for percutaneous access to the peripheral vascular system. The EVS is designed to assist in the placement and removal of therapeutic instrumentation. The device consists of three major components: a sheath with deployable mesh funnel, an obturator with deployable mesh umbrella and a hemostasis valve with luer port.

Since the EVS is designed for percutaneous insertion, patient "cut down" is unnecessary. Percutaneous insertion may be accomplished with or without the use of a standard 9F vascular introducer sheath. The EVS may also be inserted into an exposed vessel.

The EVS is substantially equivalent to the Applied Medical "Catheter Introducer Sheath" covered by K890766. The hemostasis valve portion of this product was previously approved under K895214.

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