

K962668

**NOV 4 1996** APPENDIX VIII

510(k) SUMMARY

**510(k) NUMBER:** PENDING

**SUBMITTED BY:** Applied Medical Resources Corporation  
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**DATE OF PREPARATION:** July 8, 1996

**NAME OF DEVICE:** Applied Medical Atraumax® Coronary Vascular Low Profile Clamps and Inserts.

**CLASSIFICATION NAME:** Vascular Clamp

**TRADE NAME:** Not Determined

**SUMMARY STATEMENT:** The AMR Atraumax® Coronary Vascular (ACV) low profile clamps and inserts are a line extension to an existing Applied Medical vascular clamp, model G5048. The G5048 clamp was previously approved under K901565. Differences between the ACV clamp and the predicate G5048 clamp include an expansion of the line to 5 models with sizes ranging from 45mm to 100mm and a reduction in the clamp profile. The AMR-ACV clamps are by design substantially equivalent to the G5048 clamp.

The AMR-ACV clamp is indicated for use as a clamp for partially occluding coronary vessels. The AMR-ACV clamp is of a side-bite configuration and consists of a reusable stainless steel clamp body and a set of disposable soft pad inserts. Inserts mount to the clamp via a snap fit. Mechanical and biocompatibility tests were performed to verify functional and structural integrity and material safety. All testing has demonstrated that the AMR ACV Clamp is comparable to the predicate device and introduces no new safety and effectiveness issues when used as indicated.