

K961699

AUG 23 1996

Attachment I510(k) SUMMARY OF INFORMATION:

SUBMITTER: United States Surgical Corporation
150 Glover Avenue
Norwalk, CT 06856
(203) 845-1000

CONTACT PERSON: Janet G. Johnson

DATE PREPARED: June 28, 1996

CLASSIFICATION NAME: Equipment Covers

COMMON NAME: Equipment Covers

PROPRIETARY NAME: Auto Suture* ABBI* System Equipment Cover

PREDICATE DEVICE: Sterile Equipment Covers by Custom Medical Products
(K931417)

DEVICE DESCRIPTION: Both the Auto Suture* Equipment Covers** and the Sterile Equipment Covers by Custom Medical Products (K931417) consist of various sizes and shapes of polyethylene covers which are positioned on surgical equipment. The covers are used to maintain the surgeons sterile field and as an aid in the clean up of equipment after surgery.

INTENDED USE: Both the Auto Suture* Equipment Covers** and the Sterile Equipment Covers by Custom Medical Products (K931417) are intended to cover equipment and are not intended to be as patient drapes or have patient contact.

MATERIALS: All component materials of the Auto Suture* Equipment Covers** are comprised of materials which are in accordance with ISO Standard #10993-1.

PERFORMANCE: A study was done to test the performance of the Auto Suture* Equipment Covers**. Testing consisted of an evaluation of tear resistance, puncture resistance, fluid penetration resistance and material thickness. Testing results, demonstrate that the Auto Suture* Equipment Covers** provides an acceptable fluid barrier which is resistant to puncturing, tearing and fluid penetration under normal use conditions.