K963999

United States Surgical Corporation
510(k) Premarket Notification
AUTO SUTURE* Modified Endoscopic Fascia Stapler**

SUMMARY **510(K) SUMMARY OF INFORMATION SUPPORTING SAFETY AND EFFECTIVENESS**

NOV 27 1996

SUBMITTER:	United States Surgical Corporation 150 Glover Avenue Norwalk, CT 06856 (203) 845-1000
CONTACT PERSON:	Christopher Taylor
DATE PREPARED:	October 4, 1996
CLASSIFICATION NAME:	Implantable Staple
COMMON NAME:	Surgical Staple
PROPRIETARY NAME:	Trademark name not yet determined.
PREDICATE DEVICE:	Origin® Tacker™ System (K944415)
DEVICE DESCRIPTION:	The AUTO SUTURE* Modified Endoscopic Fascia Stapler** device is an endoscopic stapling device. The device is disposable and is supplied sterile.
INTENDED USE:	The AUTO SUTURE* Modified Endoscopic Fascia Stapler** device is intended for use in affixing prosthetic material or approximating tissue. This device may be used both endoscopically and in open procedures.
MATERIALS:	All component materials of the AUTO SUTURE* Modified Endoscopic Fascia Stapler** device are comprised of materials which are in accordance with ISO Standard #10993-1.
PERFORMANCE:	The AUTO SUTURE* Modified Endoscopic Fascia Stapler** device was tested both *in-vivo* and *in-vitro* to evaluate fastener security. The results of this testing demonstrate that the subject device provides adequate fastener strength.

000

* Trademark of United States Surgical Corporation
** Trademark name not yet determined