

510(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: August 9, 1996

CLASSIFICATION NAME: Manual Surgical Instrument for general use

COMMON NAME: Trocar Cannula

PROPRIETARY NAME: Trademark name not yet determined.

PREDICATE DEVICE: Auto Suture* Modified Versaport* Trocar (K954108)

DEVICE DESCRIPTION: The Auto Suture* Cannula** is a two piece device which consists of a reusable sleeve and a disposable plastic housing with seal adapter. While the Auto Suture* Modified Versaport* Trocar (K954108) is a totally disposable trocar with cannula.

INTENDED USE: Both the Auto Suture* Cannula** and the Auto Suture* Modified Versaport* Trocar (K954108) are intended for use in a variety of gynecologic, general, thoracic, and urologic endoscopic procedures to create and maintain a port of entry.

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

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