stryker

K964930

2590 Walsh Avenue
Santa Clara, CA 95051

(408) 567-9100
(408) 567-2505 Fax

FEB 2 8 1997

Device Name:	Stryker Saphenous Vein Harvest Laparoscope
Classification	Rigid Endoscope
Sponsor	Stryker Endoscopy 2590 Walsh Ave. Santa Clara, CA 95051 FDA Registration # 2936485
Regulatory Class	Class II

Safety and Effectiveness Summary:

The Stryker Saphenous Vein Harvest Laparoscope is identical in terms of materials and modes of construction, optical performance and safety to the existing line of Stryker 5mm Laparoscopes, differing only in working length. The Stryker Saphenous Vein Harvest Laparoscope is substantially equivalent to the Snowden Pencer Saphenous Vein Endoscope in intended use and is compatible for use with the Ethicon Subcu-Retractor for this purpose.

Materials of construction coming into patient contact, including structural components and cannula components which are of stainless steel, plated brass, and anodized aluminum, joined with adhesives and braze alloys, are demonstrated to be bio-compatible per the Tripartite scheme, and/or ISO 10993 and G95-1. The optical system consisting of optical glass, adhesives and coated brass components for spacing and mounting, and light transmission fibers are identical to those currently used in Stryker cleared laparoscopes.

Stryker Saphenous Vein Harvest laparoscopes are reusable, and sold non-sterile, and are validated for cleanability, disinfection and re-sterilization. Sterilization methods include 100% EtO, Cidex® and Steris® processes. Those endoscopes labeled as "Autoclavable" will be validated for durability, cleanability, and sterilizability under specified cycles per appropriate AAMI guidelines.

The Stryker Saphenous Vein Harvest Laparoscopes present no additional safety or effectiveness issues when compared to current Stryker laparoscopes and Snowden Pencer Saphenous Vein Endocospes. Therefore, the Stryker Saphenous Vein Harvest Laparoscopes are substantially equivalent to these devices.

Bob Dahla
R&D Project Engineer