

AUG 28 1988

510(k) Notification - PortLand Trocars

K962193

Summary of Safety and Effectiveness

The PortLand Trocars is very similar to all other trocar devices previously found to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976.

Due to the increased demand for minimally invasive surgery, trocars have become an essential part of laparoscopic procedures. By providing the surgeon with a fully reusable instrument with replaceable tip such as the PortLand Trocars, SI have optimized the economy of a re-usable instrument, with the advantages of the disposable instrument, in the provision of the replaceable tip concept.

The materials used in the construction of the PortLand Trocars are commonly found in other surgical instruments and are identical with that used in the product manufactured by Mikroland. Also, the means of sterilization (autoclaving) has long been used by hospitals for the sterilization of surgical instruments.

Surgical Innovations believes this instrument is substantially equivalent to that manufactured by Mikroland which was produced under contract for Surgical Innovations, to Surgical Innovations specifications. Also, this instrument is as effective as other competitive product and does not increase the risk to the patient.