

**Section 10.0: 510(K) Summary**

APR 21 1997

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92( c ).

**10.1 Contact Person**

Cathleen Mantor

General Surgical Innovations, Inc.

3172A Porter Drive

Palo Alto, CA 94304

(415) 812-9740 extension 292

(415) 812-9731 fax

**10.2 Date Summary Prepared**

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**10.3 Trade Name**

To Be Determined

**10.4 Common Name**

Cannula with Introducer

**10.5 Predicate Device**

K903078 Hasson Stable Access Cannula. Manufacturer: Marlow Surgical Technology.

**10.6 Device Description**

GSI's Cannula with Introducer is a hand held device comprised of a Cannula with an Introducer. The Cannula is comprised of a cannula body, an inflatable valve/seal and a stopcock. The inflatable valve/seal is inflated and deflated through the stopcock. The inflatable valve/seal provides a seal for surgical tools and diagnostic instruments during minimally invasive procedures using gas insufflation. The Cannula may be supplied with either a Sharp Tip or Blunt Tip Introducer. The Introducer is used for placement of the Cannula into an endoscopic or laparoscopic surgical space.

### 10.7 Intended Use

The intended use of the GSI Cannula with Introducer is the same as the predicate devices (Hasson Stable Access Cannula K903078). The intended use of the predicate device and the GSI Cannula with Introducer is to provide access for surgical and diagnostic instruments for the duration of a surgical procedure.

### 10.8 Comparison to Predicate Devices

	<b>Predicate Device Stable Access Cannula (K903078)</b>	<b>GSI's Cannula with Introducer</b>
Intended Use	Access for minimally invasive procedures	Access for minimally invasive procedures
Principles of Operation	Insertion through incision, under direct visualization (when possible) when using sharp tip	Insertion through incision, under direct visualization (when possible) when using sharp tip
Design: -cannula -valve/seal -anchoring -method -insufflation port	rigid flexible valve and seal inflatable balloon type  included	flexible inflatable, flexible valve/seal screw type  not included
Materials	molded rigid plastic, elastomeric polymer and stainless steel	molded rigid plastic, elastomeric polymer and stainless steel
Supplied	Sterile, 5 devices/box w/5mm reducer,  disposable	Sterile, 5 devices/box, inflatable valve/seal provides reducer function, disposable
Introducer Type	blunt & sharp	blunt & sharp
Cannula Lumen	10/12 mm	10 mm
Compliance w/Standards	No known standards	No known standards

### 10.9 Testing in Support of Substantial Equivalence Determination

Results of performance bench tests verify that the differences between the Cannula with Introducer and the predicate device do not affect the safety or efficacy of the GSI Cannula with Introducer.