

**1. Submitter Name, Address, and Date of Submission:**

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JAN 10 1997

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Contact: Same as above.

**2. Names of the Device, Common, Proprietary(if Known), and Classification.**

Classification Name: Secondary Trocar with Sleeve

Common Name: Secondary Trocar and Sleeve with Insufflation Port

**3. Identification of the legally marketed device to which the submitter claims equivalence.**

The Pilling Weck Secondary Trocar and Sleeve with Insufflation Port are substantially equivalent to the Core Dynamics Entree II, Access Surgical Access Single Use Trocar and Sleeve, United States Surgical Acute Suture Surgiport™ Disposable Surgical Trocar and Cannula with Insufflation Port, and Karl Storz Trocars and Cannula with Insufflation Ports.

**4. Description of the Device:**

The device consists of a Secondary Trocar and Sleeve with Insufflation Port with mounted cap. The cap consists of a universal adapter seal with reducer, which is used as a port of entry for the instrument/probe and used to minimize leakage and loss of pneumoperitoneum.

The Secondary Trocar is constructed with a stainless steel tip and is available in pyramidal style and has a polymer handle and upper shaft.

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The Sleeve, proportionally sized, is made of polymer, threaded and contains an insufflation port . There is a mounted cap assembly, which has a universal adapter seal with guiding port and reducer.

#### **5. Intended Use of the Device:**

The Secondary Trocar and Sleeve with Insufflation Port are manual surgical instruments used to support a cut down(lap approach). The secondary trocar is used in Endoscopic Surgery(Abdominal and Thoracic) for incision and peritoneal access for positioning of the hollow sleeve.

Once the trocar is removed, the port of entry provided by the sleeve, through the cap, is used with manual surgical instruments, endoscopic instruments, laproscopes, and probes. There is an seal on the cap, which closes the port of entry.

The usage of this product is identical to previous devices, which have the same technological characteristics.

#### **6. Summary of Technological Characteristics:**

The following technological characteristics are the same or equivalent as predicate devices:

The Trocar, consisting of a hub with a stainless steel tip are equivalent to the predicates.

The sleeve with insufflation port and cap assembly, which has the port of entry for the surgical instrument and has a threaded shaft, is used with the Trocar, which is equivalent to the predicates.

The Cap Assembly is contains the seal, which is used to minimize the leakage from the pneumoperitoneum, which is equivalent to the predicates.

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