

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

Miss Karenann J. Brozowski
Group Regulatory Affairs Director
Pilling Weck Group
Tall Pines Park
Jaffrey, NH 03452

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Telephone: (603)532-7706

Contact: Same as above.

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

Classification Name: Secondary Trocar with Sleeve

Common Name: Reusable Trocars and Cannula with Insufflation Port

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

The Pilling Weck Trocars and Cannula with Insufflation Port are substantially equivalent to the Core Dynamics Entree II, Access Surgical Access Single Use Trocar and Sleeve, Mahe Reusable Standard Trocar and Trumpet Valve Cannula, Mahe Safety Trocar.

4. Description of the Device:

The device consists of Reusable Trocars and Cannula with Insufflation Port with available Single Use Disposable Caps. The Disposable Cap Assembly consists of a universal adapter seal, which is used as a port of entry for the instrument/probe and used to minimize leakage and loss of pneumoperitoneum.

The Disposable Cap Assembly is packed sterile in individual pouches or two to a pouch.

The Reusable Trocars are constructed with a stainless steel shaft and are available in pyramidal style. The Reusable Shielded Trocar is available with a conical or pyramidal tip.

The Sleeve, proportionally sized, is made of polymer and accepts the Disposable Cap Assembly to seal the port of entry for the surgical instrument.

5. Intended Use of the Device:

The Reusable Trocars and Cannula with Insufflation Ports are manual surgical instruments used to support a cut down(lap approach). The trocar is used in Endoscopic Surgery(Gynecologic, general and other laparoscopic procedures 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 Reusable Trocars, consisting of a hub with a stainless steel shaft are equivalent to the predicates.

The cannula with insufflation ports used with the Trocar is treaded, 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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