

510(k) Summary

This summary of safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

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1. Submitter:

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2. Device:

Propriety Name SPIDER™ Surgical Instruments
 Common Name Laparoscopic instrument and accessory
 Classification Name: Endoscope and accessories
 Classification: Class II 21 CFR 876.1500
 Product Code: GCJ

3. Predicate Device:

Snowden-Pencer	Reusable Laparoscopic Instruments
Olympus	FG Series Grasping Forceps and Surgical Scissors
Novare	RealHand High Dexterity Instruments
Weck	Hem-O-Lok™ Ligating Clip Applier
US Surgical	Autosuture™ Endo Clip III Clip Applier
Cabot Medical	Surgiflex Wave Suction Irrigation Probe

4. Description:

The SPIDER™ Surgical Instruments are surgical instruments to facilitate laparoscopic surgery. They are intended for use with the SPIDER™ Single Port Device or other laparoscopic access device that facilitates the use of rigid and/or flexible instrumentation.

The surgical instruments may be categorized as follows:

- Rigid instruments
- Flexible instruments
- Flexible Electrocautery or energy instruments

1. Rigid Surgical Instruments

The rigid instrument set includes a rigid grasper for grasping, mobilizing, or retracting tissue. It is a re-usable device that is provided to the user non-sterile with instructions for cleaning and autoclaving.

2. Flexible Instruments

The flexible instruments are pre-sterilized, single use disposable devices. The devices are ethylene oxide sterilized. The flexible instrument set includes:

- Flexible grasping forceps for grasping, mobilizing, or retracting tissue
- Flexible dissecting forceps for dissecting tissue
- Flexible scissors for cutting tissue
- Flexible 5mm clip applier for ligation
- Flexible suction/irrigation probe to deliver sterile irrigation fluids and evacuate blood, tissue debris, and smoke from the surgical site

3. Flexible Electrocautery Instruments

The flexible electrocautery instruments are pre-sterilized, single use disposable devices. The devices are ethylene oxide sterilized. The electrocautery instrument set includes:

- Flexible monopolar electrocautery instruments for cutting and coagulation of tissue

5. Indications for Use:

The SPIDER™ Surgical Instruments are intended for use in minimally invasive surgical procedures for grasping, mobilizing, dissecting, retracting, cutting, cauterizing, ligating, suction/irrigation and other manipulation of tissues and vessels during a laparoscopic procedure under direct and/or endoscopic visualization.

6. Comparison of Technological Characteristics with Predicate:

The SPIDER™ Surgical Instruments have the same intended use and function of other currently marketed laparoscopic and endoscopic surgical instruments. Like the predicates the instruments have the same end effector/jaw/tip designs. The devices achieve the same function using the same modes of action. The rigid and flexible instruments are passed through the TransEnterix cannulas (IDTs) and advanced to the surgical site, exactly in the same manner as other surgical devices are passed through conventional trocars/cannulas used in standard single port or multi-port laparoscopic surgery.

The SPIDER™ Flexible Instruments utilize the same or similar design, dimensions, materials of construction, and sterilization as that of the predicates. Similar to the predicate devices the SPIDER™ Flexible Instruments are provided pre-sterilized, are disposable, and are single use devices, the same as other predicate devices. Similar to the predicate devices the SPIDER™ Rigid Grasper is provided non-sterilize and is cleaned and autoclaved between uses the same as the predicate device.

The flexible design and length of the SPIDER™ Flexible Instruments are essentially the same as other predicate devices currently marketed. The design of the devices, in terms of length and flexibility, allows both groups of devices to achieve access to the surgical space through a trocar and perform their intended functions in a similar manner. The slight difference in shaft length does not present any new issues of safety or efficacy.

Any technological differences between the SPIDER™ Surgical Instruments and the predicates have been mitigated via testing. Thus the SPIDER™ Surgical Instruments do not introduce any new issues of safety or effectiveness compared to other similar laparoscopic or endoscopic surgical devices currently marketed.

7. Performance Data:

The SPIDER™ Surgical Instruments have been functionally tested in bench top simulation studies and found to perform their intended functions for laparoscopic surgical procedures.

The SPIDER™ Flexible Instruments have been tested for sterility using ethylene oxide to demonstrate the ability to sterilize and produce a sterility assurance level of 1×10^{-6} . The SPIDER™ Rigid Grasper has been tested for cleaning and autoclave sterilization to assure safety of multiple uses. The SPIDER™ Instruments have been tested for biocompatibility in accordance with ISO 10993-1 based on type and duration of contact to assure that they are non-cytotoxic, non-sensitizing and non-irritating. The SPIDER™ Electrocautery Instruments have been tested for compliance to IEC 60601-2-2 and found to be capable of operation up to a maximum voltage of 3500 Volts peak. The

The SPIDER™ Surgical Instruments have been tested in a pre-clinical swine study to compare their performance to that of standard laparoscopic instruments and to assure their performance and success in laparoscopic procedures. When compared to the predicate devices, the SPIDER™ Surgical Instruments do not incorporate any significant technological differences that affect safety and efficacy, therefore, clinical data was not deemed necessary for evaluation of substantial equivalence.

These verification and validation test results are sufficient to demonstrate safety and effectiveness compared to predicate devices used in standard laparoscopic surgical techniques. Any minor technological differences in the design or materials of the SPIDER™ Surgical Instruments have been evaluated and found to present no new issues of safety and effectiveness.

8. Conclusion:

The conclusion drawn from the test data is that the SPIDER™ Surgical Instruments are as safe and effective as the predicate devices, perform similarly to other legally marketed predicate devices for laparoscopic surgery, and do not raise any new issues of safety or effectiveness.