K965121



MAR 20 1997



## 510(k) SUMMARY OF SAFETY & EFFECTIVENESS

This 510(k) Summary details sufficient information to provide an understanding of the basis for a determination of substantial equivalence. For convenience, the summary is formatted pursuant to 21 CFR §807.92. This section may be used, as presented, to provide a substantial equivalence summary to anyone requesting it from the Agency.

**21 CFR §807.92 a(1)**

Submitter: ORIGIN® Medsystems, Inc.
135 Constitution Avenue
Menlo Park, CA 94025
(415) 617-5142
contact person: Anthony Durso
date prepared: December 20, 1996

**21 CFR §807.92 a(2)**

Trade name: To Be Determined

Common name: Cannula
Classification name: Manual Surgical Instrument

**21 CFR §807.92 a(3)**

Identification of predicate(s): Substantial equivalence for the Multi-Port Cannula is based on its similarities to predicate device : the ORIGIN Endoscopic Visualization and Space Maintenance Cannula . It shares the identical material, and technological characteristics as the predicate device. The Multi-Port Cannula is also similar in intended use.

**21 CFR §807.92 a(4)**

Device Description-parts and function/concept: The Multi-Port Cannula is a single- use device which consists of two movable working cannulas, seals, a stabilizer, two stationary cannulas, leur fitting, and an insufflation tube. The two movable working cannulas passes completely through the stationary cannulas which are casted to the stabilizer. The seals within the inner wall of the cannulas seal on surgical devices that are inserted through the cannulas. The stabilizer provides a seal against the tissue at the incision site and acts to stabilize the cannulas. Surgical access is achieved via standard incision. The Multi-Port Cannula is assembled and advanced

through the incision site. The user may then advance endoscopic tools through the working cannulas or stationary cannulas to perform the procedure. The Origin Multi-Port Cannula has applications in minimally invasive surgery to provide a port of access during endoscopic procedures.

Device Description-materials/physical properties: a table of the patient contact components, with their respective materials, is provided below.

| Component Name | Patient Contact | Material | Predicate |
|---|---|---|---|
| Stabilizer | yes | Sponge | Carwild Corp. Disposable Specialty Sponges k913302 |
| Stationary Cannulas | yes | Polycarbonate | Endoscopic Visualization and Space Maintenance Cannula k964632 |
| Working Cannulas | yes | Polycarbonate | Endoscopic Visualization and Space Maintenance Cannula k964632 |
| Stationary Cannula Seals | yes | Silicone Rubber | Respoable Trocar (T5) k960936 |
| Working Cannula Seals | no | Silicone Rubber | Respoable Trocar (T5) k960936 |
| Adhesive | no | Silicone Adhesive | Blunt Tip Surgical Trocar k924011 |
| Leur Fitting | no | Polyurethane | Airlift™ Balloon Retraction System k942678 |
| Insufflation Tube | yes | Polyurethane | Airlift™ Balloon Retraction System k942678 |

The listed parts are currently being used in existing ORIGIN products, and therefore have been cleared for biocompatibility (safety) and effectiveness.

**21 CFR §807.92 a(5)**

Intended use and relationship to predicate(s): The Origin Multi-Port Cannula has applications in minimally invasive surgery to provide a port of access during endoscopic procedures.

The predicate device (Endoscopic Visualization and Space Maintenance Cannula ) has applications in minimally invasive surgery and is primarily indicated for patients undergoing endoscopic surgery including laparoscopy and thoracoscopy.

The Multi-Port Cannula is not intended for use except as indicated. In addition, it is not intended for use when endoscopic surgery is contraindicated.

**CFR §807.92 a(6)**

Technological characteristics and relationship to predicate(s):
The Multi-Port Cannula is substantially equivalent to the Endoscopic Visualization and Space Maintenance Cannula previously exempted product. The Multi-Port Cannula shares the, technological characteristics and materials as the predicate device.

**21 CFR §807.92 b**

This submission's determination of substantial equivalence is based on similarities to the predicate devices in terms of intended uses, materials, and technological characteristics.

**21 CFR §807.92 c**

In accordance with the specifications of this subsection, this summary (4 pages) is its own section, and has been clearly identified as such.