K962104

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)

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21 CFR §807.92 a(2)

Trade name: Airlift Jr.™ Balloon Retraction System

Common name: Retraction Instrument
Classification name: Retraction Instrument

21 CFR §807.92 a(3)

Identification of predicate(s): Substantial equivalence for the Airlift Jr.™ Balloon Retraction System is based on its similarities to predicate device : the ORIGIN Airlift™ Balloon Retraction System. The Airlift Jr.™ Balloon Retraction System, shares the identical material, and technological characteristics as the predicate device. The Airlift Jr.™ Balloon Retraction System is also similar in intended use.

21 CFR §807.92 a(4)

Device Description-parts and function/concept: The Airlift Jr.™ Balloon Retraction System is a single-use device which consist of an inflatable balloon, balloon sheath, tether and scrap, inflation bulb, and an attachment assembly which includes a connector drape and tool holder. The Airlift Jr.™ Balloon Retraction System is provided sterile and is developed to be used in conjunction with an Origin Laparolift Retraction System. This device is used to lift and retract organs and tissues to provide a space for endoscopic surgery without the use of gas insufflation.

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Device Description-parts and function/concept: continued

The retraction of organs and tissues is achieved by first making a small incision then inserting the Airlift Balloon device. The Airlift Balloon is then attached to the Laparolift (mechanical distention arm) by means of the attachment assembly (tool holder and connector drape). The Laparolift is used to lift the Airlift Balloon device, and therefore the organs and tissues are raised to the height typically achieved by gas insufflation thus creating a working cavity for surgery. This function is equivalent to those described for the predicate device: Airlift™ Balloon Retraction System k942678, same as (Lifting Distention Balloon System, the predicate device will be refered to hence forth as Airlift™ Balloon Retraction System). The new device: Airlift™ Jr. has a balloon size of 4.1 inches deployed. The predicate device: Airlift™ Balloon Retraction System has a balloon size of 5.4 inches deployed. (See comparable chart on page 16-17).

Device Description-materials/physical properties: a table of the patient contact components, with their respective materials, is provided below. The connector drape, tool holder and Laparolift (mechanical distention) arm are the same as those cleared in the K921103, 1/15/93.

Component Name	Patient Contact	Material	Predicate
Inflation Balloon	yes	polyurethane coated nylon	Airlift™ Balloon Retraction System, k942678
Containment Sheath	yes	polyurethane	Airlift™ Balloon Retraction System, k942678
Tether and Strap	yes	polyurethane coated nylon	Airlift™ Balloon Retraction System, k942678
Tube Inflation	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 Airlift Jr.™ Balloon Retraction System has applications in minimally invasive surgery. It is indicated when endoscopic surgery is indicated and may be used as an alternative to insufflation for retracting organs and tissues thus creating a working cavity for endoscopic surgery. The Airlift Jr.™ Balloon Retraction System is used in conjunction with the Laparolift™ previously cleared under premarket notification k921103 September 9, 1993. The predicate device (Airlift™ Balloon Retraction System) has applications in laparoscopic surgery and is indicated and may be used as an alternative to insufflation for retracting organs and creating a working cavity for laparoscopic surgery. The predicate device is also used in conjunction with the Laparolift™ .

The Airlift Jr.™ Balloon Retraction System 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 Airlift Jr.™ Balloon Retraction System is substantially equivalent to the Airlift™ Balloon Retraction System previously cleared product. The Airlift Jr.™ Balloon Retraction System shares the identical function, 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.