

K 960936

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: Resposable Trocar System
[5mm, 5mm short, 10mm and 12 mm sizes]
Common name: Reposable Surgical Trocar
Classification name: Laparoscope, Gynecologic and Accessories

21 CFR §807.92 a(3)

Identification of predicate(s): Substantial equivalence for the Resposable Trocar System is based on its similarities to predicate device : the ORIGIN Sensing Tip Trocar (OMS-T5S, OMS-T10S, OMST1112S). The Resposable Trocar System, shares the identical intended use, and technological characteristics as the predicate device. The Resposable Trocar System is also identical in materials except for the reusable cannula. It is stainless steel versus a polycarbonate on the 10mm and 12mm and liquid crystal polymer(LCP) on the 5mm cannula of the Sensing Tip Trocar.

21 CFR §807.92 a(4)

Device Description-parts and function/concept: **The Origin Sensing Tip Resposable Trocar System** is a single-use obturator and seal provided sterile, used in conjunction with an Origin Reusable Cannula of the same size, provided non-sterile. When assembled, this device is used to puncture the incision site and to provide a port of access for insertion of endoscopic

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Device Description-parts and function/concept: continued

instruments. The trocar consists of a sharp, pyramidal tip connected to an obturator and handle, with an integral safety mechanism. As the tissue is penetrated, the tip withdraws into the cannula to help protect internal organs from exposure to the sharp tip. The disposable seal consists of an internal valve to prevent gas leakage when instruments are inserted or withdrawn. The 10mm and 12mm seal will include a built-in converter cap to prevent leakage and allow insertion of instruments of different diameters than the main seal. The seal is to be assembled with the Origin Reusable Cannula. The Reusable Cannula will be available with or without an external valve for gas insufflation, and an external gripping mechanism to assist in retaining the device in the incision site. The cannula is to be assembled with the disposable seal. The Reusable Cannula will be available in four sizes 5mm, 5mm short, 10mm and 12mm.

Device Description-parts and function/concept: The Origin Classic Tip

Resposable Trocar System is a single-use obturator and seal provided sterile, used in conjunction with an Origin Reusable Cannula of the same size, provided non-sterile. When assembled, this device is used to puncture the incision site and to provide a port of access for insertion of endoscopic instruments. The trocar consists of a sharp, pyramidal tip connected to an obturator and handle. The disposable seal consists of an internal valve and seal to prevent gas leakage when instruments are inserted or withdrawn. The 10/12mm Seal will include a built-in converter cap to prevent leakage and allow insertion of instruments of different diameters than the main seal. The seal is to be assembled with the Origin Reusable Cannula. The Reusable Cannula will be available with or without an external valve for gas insufflation, and an external gripping mechanism to assist in retaining the device in the incision site. The cannula is to be assembled with the disposable seal. The Reusable Cannula will be available in four sizes 5mm, 5mm short, 10mm and 12mm.

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

Component Name	Material(s)
Cannula	stainless steel
Obturator Shaft	polycarbonate
Obturator Point	stainless steel

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 Responsible Trocar System has applications in endoscopic surgery, for establishment of a port of entry for endoscopic instruments. It may be used for endoscopic transabdominal, extraperitoneal, thoracoscopic, gynecologic or abdominal procedures. The Reusable Cannula must be used in conjunction with a complete Origin Trocar of the same size. The Sensing Tip Trocar has applications in gynecologic and abdominal surgery for puncture of the abdominal cavity and establishment of a port of entry for endoscopic instruments.

During abdominal surgery the Responsible Trocar is inserted through the abdominal wall and the trocar cannula is left in place to allow the passage of endoscopes and other endoscopic instruments. This function is equivalent to those described for the predicate device: the Sensing Tip Surgical Trocar.

The Responsible Trocar 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 Resposable Trocar System is substantially equivalent to the Sensing Tip Surgical Trocar previously cleared product. The new device shares the identical technological characteristics as the predicate device. The Resposable Trocar is also identical in materials except for the reusable cannula. It is stainless steel versus a polycarbonate cannula on the 10mm and 12mm and liquid crystal polymer (LCP) on the 5mm Sensing Tip Trocar.

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.