

ORIGIN Medsystems, Inc.
PREMARKET NOTIFICATION

VasoView™ Balloon Dissection System

K964171

Class II

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: VasoView™ Balloon Dissection System

Common name: Dissection Cannula

Classification name: Distention Balloon

21 CFR §807.92 a(3)

Identification of predicate(s): Substantial equivalence for the VasoView™ Balloon Dissection System is based on its similarities to predicate device : the ORIGIN Tapered Tip Balloon Dissection Cannula . It shares the identical material, and technological characteristics as the predicate device. VasoView™ Balloon Dissection System is also similar in intended use.

21 CFR §807.92 a(4)

Device Description-parts and function/concept: The VasoView™ Balloon Dissection System is a single-use device which consist of a, tubular body with a distal transparent conical tapered tip, an elastomeric balloon adjacent to the tapered tip, luer extension, and syringe. It is designed to accept a 5mm diameter rigid endoscope for visualization through the tapered tip. The VasoView™ Balloon Dissection System is provided sterile This dissection cannula is used to advance along specific anatomic tracts to isolate structures. After the cannula advancement, sequential balloon inflation forms an elongated cavity in the desired location.

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
Cannula	yes	Polycarbonate	Tapered Tip Balloon Dissection Cannula k953377
Balloon	yes	Silicon Latex Rubber	Tapered Tip Balloon Dissection Cannula k953377
Adhesive	yes	Loctite™	Tapered Tip Balloon Dissection Cannula k953377

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 VasoView™ Balloon Dissection System has applications in minimally invasive surgery. It is indicated when endoscopic surgery is indicated and may be used to form elongated working cavities during thoracoscopic procedures involving exposure and dissection of structures external to the parietal pleura, including, nerves, blood vessels and other tissues of the chest wall. The predicate device (Tapered Tip Balloon Dissection Cannula) has applications in minimally invasive surgery and is primarily indicated for patients undergoing laparoscopic surgery requiring tissue separation of the extraperitoneal space or extremities.

The VasoView™ Balloon Dissection 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 VasoView™ Balloon Dissection System is substantially equivalent to the Tapered Tip Balloon Dissection Cannula previously cleared product. The VasoView™ Balloon Dissection 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 (3 pages) is its own section, and has been clearly identified as such.