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: Mr. Anthony Durso
date prepared: February 7, 1996

21 CFR §807.92 a(2)

Trade name: 5mm Endoscope
Common name: Endoscope
Classification name: Endoscope and/or Accessories

21 CFR §807.92 a(3)

Identification of predicate(s): Substantial equivalence for the 5mm Endoscope is based on its similarities to the predicate: the ORIGIN Small Diameter Endoscope. The 5mm Endoscope shares the same intended use as the predicate device. The 5mm Endoscope also is similar to the predicate device in terms of materials and technological characteristics.

21 CFR §807.92 a(4)

Device Description-parts and function/concept: The 5mm Endoscope is a rigid endoscopic device which is comprised of a shaft, scope body, illuminator port, eyepiece, light fiber optics, image rod, and front window. The 5mm Endoscope is a rigid endoscope which may be used to visualize the interior of body cavity or surgical working cavity during endoscopic procedures. The endoscope may also be used in conjunction with surgical devices which accept a 5mm diameter endoscope as their visualization component.