

## 510(k) Summary

K965055

MAR - 6 1997

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**Summary Preparation:** December 17, 1996

**Device:** MicroLap™ and MicroLap Gold Laparoscopes

**Predicate Devices:** Imagyn MicroLap Laparoscope  
Medical Dynamics Optical Catheter  
Optimed Technologies Model F18-200 Laparoscope  
Origin Medsystems, Inc. Small Diameter Endoscope  
Galileo Endoscope

**Device Description:** The MicroLap™ and MicroLap Gold Laparoscopes are small diameter, rigid, fiberoptic laparoscopes without through lumens. The devices consist of an outer stainless steel shaft, inner illumination fibers, and an imaging fiber bundle. At one end of the imaging bundle is the distal lens and at the other is the rotatable eyepiece. An endoscopic light source is connected to the light post of the laparoscopes through compatible light cables. If desired, the eyepiece can be connected through a focusing optical coupler to a camera head which carries the image by cable to the camera.

**Intended Use of Device:** The MicroLap™ and MicroLap Gold Laparoscopes are used to permit viewing of the abdominal cavity for the purpose of performing diagnostic and surgical procedures.

**Technological Comparisons:** Light from a high intensity light source (e.g. xenon) is transmitted through illumination fibers to the distal end of the laparoscope in order to illuminate the target object. The distal lens system focuses the image of the object onto image fibers, which then transmits the image to the proximal lens system. The proximal lens system magnifies and focuses the image onto an eyepiece at the proximal end of the laparoscope for viewing and/or directly to standard video cameras, monitors and recording equipment. The MicroLap™ and MicroLap Gold Laparoscopes and the predicate devices all have equivalent technological characteristics.

**Performance Summary** Non-clinical tests were performed to demonstrate that the device performed according to its description. Testing included evaluation of optical and mechanical characteristics of the device and the effect of simulated reuses on these characteristics. The device was also evaluated for its thermal characteristics and biocompatibility.

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