

FEB - 7 1997

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510(k) Summary: #K962246

- 1) **Submitter:** Saber Endoscopy, L.L.C.
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- Date Prepared:** November 14, 1996

- 2) **Name of Device:** Rigid Fiber Optic Laparoscope
- Proprietary/Trade Name:** (Not yet determined)
- Common/Usual Name:** Laparoscope
- Classification:** Class II (21 CFR §884.1720)
- Classification Name:** Laparoscope, Gynecologic

3) **Name of Predicate or Legally Marketed Devices:**

Saber's Rigid Fiber Optic Laparoscopes are substantially equivalent to the following predicate devices:

- Imagyn Medical, Inc.
MicroLap™ Laparoscope
Approved by FDA for marketing on 20-Jan-95 under 510(k) # K944079.
- Olympus America, Inc.
Mini Laparoscope for General Surgery
Approved by FDA for marketing on 01-Feb-95 under 510(k) #K950278.
- Optimed Technologies, Inc.
OptiMIS® Series 300 Rigid Fiber Optic Laparoscopes
Approved by FDA for marketing on 23-Nov-92 under 510(k) #K921883 for abdominal laparoscopy and other indicated uses, and on 12-Jul-94 under 510(k) #K926597 for gynecologic laparoscopy.

4) **Description of Device:**

Saber Endoscopy's Rigid Fiber Optic Laparoscopes are small diameter endoscopes which consist of fiber optic imaging fibers and illumination fibers contained within a stainless steel jacket. Light from a high intensity light source is transmitted to the scope by a detachable light carrying cable. The light is then carried by the illumination fibers to the target. A distal lens focuses an image of the target onto the image fiber bundle. The image is transmitted to the proximal end of the scope, where it is magnified and focused by an optical eyepiece. The image may be viewed directly through the eyepiece, or the scope may be connected to a video system via a standard endoscopic video coupler.

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5) **Intended Use of Device:**

Saber's Rigid Fiber Optic Laparoscopes are used to permit direct viewing of the organs within the peritoneal cavity for the purpose of performing diagnostic and surgical procedures.

6) **Comparison of Technological Characteristics:**

Saber's Rigid Fiber Optic Laparoscopes are substantially equivalent¹ to the predicate or legally marketed Imagyn MicroLap Laparoscope, Olympus Mini Laparoscope for General Surgery, and Optimed Series 300 Rigid Fiber Optic Laparoscopes. Saber's scopes employ the same design considerations and operating principles as the predicate devices, and each can be sterilized and reused. Any differences between the Saber, Imagyn, Olympus and Optimed laparoscopes do not raise new questions regarding safety or effectiveness.

¹The term, "substantially equivalent," is intended to reflect a determination of substantial equivalence under the Federal Food, Drug, and Cosmetic Act, and relates to the fact that the product can be marketed without premarket approval or reclassification. Such a determination is not intended to have any bearing on matters relating to patents.