



JUL - 5 1996

510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92"

The Surgical Image Laboratories Laparoscope is equivalent in materials, intended use, safety and effectiveness to the Dyonics 8000 Laparoscope

The outer tube of the Surgical Image Laparoscope are fabricated from 304 stainless steel. This stainless steel, often referred to as "Surgical Steel" has been used in various medical and surgical procedures for many years, including existing laparoscopes, as was chosen for the Surgical Image Laparoscope because it is non-reactive with the human body, is easy to clean and sterilize, and poses no danger to the patients as long as it is prepared for use appropriately and used by a qualified professional trained technician.

The block and light adapter are made from plated brass and the I.D. ring from anodized aluminum.

As with laparoscopes existing before Surgical Image's Laparoscope, the distal end tip of the laparoscope that is inserted into the body through a small incision during surgery is fabricated from optical glass which may be coated with an anti-reflective coating to reduce or eliminate glare during the surgical procedure. The glass and the coating applied thereto also are non-reactive with the human body and pose no danger to the patient.

As with laparoscopes existing before Surgical Image's Laparoscope, the optic tube which fits within the outer tube is fabricated from stainless steel. Although this tube is covered at the tip by the distal window and therefore does not come into contact with internal body organs, it is still fabricated from a material that is non-reactive with human tissue and which poses no danger to the patient.

As with laparoscopes existing before Surgical Image's Laparoscopes, the distal fiber which transmits light from the light source through the fiber cone, around the optic tube, and on to the surgical area is fabricated from optical fibers and sealed at the distal end with adhesive. Nevertheless, these materials are again non-reactive with human tissue and pose no danger to the patient.

As with laparoscopes existing before Surgical Image's Laparoscopes, the eye shield or camera connection adapter is made from acetal plastic or an FDA accepted equivalent.

As with laparoscopes existing before Surgical Image's Laparoscopes, all surfaces of the Surgical Image's Laparoscope are smooth and polished or bead blasted to provide a cosmetically accepted surface. The end of the instrument that is inserted into the human body through an incision is blunt or rounded with no sharp edges.

The Surgical Image's Laparoscope is a totally benign instrument that in and of itself does not and cannot put a patient at any risk of injury when it is used for its intended purpose by properly trained and qualified personnel.

The Surgical Image's Laparoscope is substantially equivalent to laparoscopes that are manufactured by such companies as Olympus Corporation, Richard Wolf Medical Instruments Corporation, Karl Storz Endoscopy, Smith & Nephew Dyonics, and Stryker Endoscopes, and which have now been in the marketplace in the United States and throughout the world for many years.


Zoltan Barazs
President