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Classification Name: Surgical Lamp
Common and usual name: Light source, projector, Illuminator
Proprietary Name: Q-5000

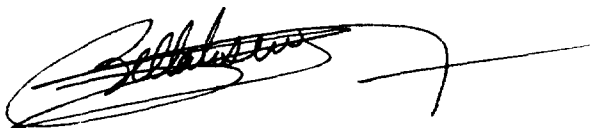
SUMMARY OF SAFETY AND EFFECTIVENESS STATEMENT

The Stryker Endoscopy Q-5000 light source is used to illuminate the site of surgery during minimally invasive surgical procedures in arthroscopy (orthopedic surgery), laparoscopy (general and gynecological surgery), and endoscopy (general, gastroenterological and ENT surgery). The light is transmitted from the source through an optical cable and a scope. The light source is an integral component of a visualization system which consist of the a video camera, a video monitor, a light cable and a scope.

The Q-5000 light source is AC powered and is designed to meet international medical devices safety standards (IEC 601-1, UL, CSA) to provide safe operation and eliminates or minimizes risks of burns, fire, explosion eye damage, electromagnetic interference or electrical shock that may be associated with it.

Light sources have been used in endoscopic surgical procedures for at least 15 years. They have been safe and effective to provide adequate lighting to surgical sites.

The Stryker Endoscopy Q-5000 light source is substantially equivalent to the Circon-ACMI MV9082 light source and raises no additional safety or effectiveness issues.



Bader Bellahsene, Ph.D.
Project Engineer

05/17/96