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Cogent Light Technologies 510(k) Premarket Notification for the XLS Illuminator System  
510(k) Number: K 971057

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS:**

**A. Safety:**

The Cogent Light XLS Illuminator System is designed with a safety interlock on the lamp (XLF) access cover. If the cover is opened, the power to the illuminator will be interrupted. The instrument is cooled with a forced air fan to prevent the temperature of the unit from exceeding a safe level. If in the event that the fan malfunctions and fails to operate properly and the internal temperature of the illuminator exceeds the engineered specifications, the device is designed with an internal thermal protection mechanism that automatically shuts off the power to the unit.

The lamp (XLF) with fixture and power source may fail passively (i.e., just not turn on, or just go out). Typically, lamp and power source defects do not result in lamps going out during a surgical case. It is more likely that a lamp cannot be turned on during preparation for a surgical case. The consequences is that this would cause an inconvenience and a time delay. However, it is expected to result in no adverse medical condition in the patient.

To minimize such inconveniences, the XLS Illuminator System contains a user replaceable lamp (XLF) and would encourage the operator to have a spare lamp available on site.

The lamp (XLF) may fail in a non-passive mode, resulting in an audible sound which may startle the user. Due to the inherent nature of all short arc Xenon lamps, including those found in the predicate device, it is impossible to guarantee against all such failures, although they are rare.

To minimize such events, the XLS system has incorporated several safety features into the product design. These safety features include:

- (1) The lamp is never operated beyond its specified power range.
- (2) The lamp is limited to 650 operating hours by a system timer. This limit is significantly below the safe rated life expectancy of the lamp (approximately 1000 hours) as stated by the lamp manufacturer.
- (3) The housing of the system has interior structures (baffles), which will dampen the sound level and confine any debris which might result from the non-passive lamp failure.
- (4) The user replaceable Lamp Housing Module (XLF) would minimize the inconvenience.

**B. Effectiveness:**

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All Xenon arc lamps produce light that is spectrally similar to sunlight. What is actually delivered to an endoscope, surgical headlight, or surgical instrument, is determined by optical coatings and the transmissive properties of the light delivery system (single or bundle fiber).

The XLS Illuminator uses a proprietary single fiberoptic cable. A single multimode fiber typically produces a uniform image at the output end independent of the intensity profile of the light on the input end. By contrast, fiber bundles produce non-uniform images because they consist of many fibers bonded together, producing spaces between the fibers and generally low light intensity at the very center. Any application involving direct illumination (e.g., surgical headlamp) requires preferably uniform illumination.

Fiber bundles have been the standard light delivery system in use. Liquid bundles are somewhat more transmissive, but substantially more expensive. Light delivered through a fiber bundle is attenuated more in the blue than the red,

producing a more yellow light than that from a liquid bundle. Cogent Light Technologies' single quartz fiber, used as part of the subject device, as well as the predicate device, transmits white light uniformly throughout the visible spectrum.

**C. SUMMARY:**

Cogent Light Technologies believes that the Cogent Light XLS Illuminator System is substantially equivalent in design, component materials, function, labeling, and intended use to the Cogent Light Technologies Illuminator System.

Both devices are intended for the same use, that of providing visible light for the illumination of surgical headlights and various rigid or flexible endoscopes that contain fiber bundles for illumination. Applications for both systems include, but are not limited to, externally illuminated endoscopes used in arthroscopy, bronchoscopy, gynecology, laparoscopy, obstetrics, oto-rhino-laryngoscopy, urology, and vascular endoscopy.

Both devices consist of a light source control box which houses a Xenon lamp, power supply, and connects to a proprietary fiberoptic cable. With a fiber bundle adapter, this illuminator can also be used with regular fiber bundle optic cables and headlamps.

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