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Premarket Notification [510(k)] Summary

LSI Solutions
2144 Brighton-Henrietta Town Line Road
Rochester, NY 14623
Phone: 716-427-7979
Fax: 716-427-7482
Contact: Jude S. Sauer, M.D.

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Trade Name: LSI Videoscopic Display System

Common Name: Color Video Monitor

Classification Name: Surgical Camera and Accessories (per 21 CFR Section 878.4160)

Predicate Device: The legally marketed device (predicate) to which substantial equivalence is claimed is the Sony Trinitron Color Video Monitor, Model Number PVM-1343MD (K5885042).

Description: The LSI Videoscopic Display System utilizes advanced video projection technology to display an image on a sterile, disposable screen appropriately positioned within the surgical field.

Intended Use: The LSI Videoscopic Display System produces high quality video images for use in a wide range of medical applications, including surgery, microscopy and endoscopy.

Comparison:

Summary of the technological characteristics of how this device compares to the predicate device:

| Specification | LSI Videoscopic Display System (Model 001) | Sony Color Video Monitor (PVM-1343MD) |
|--------------------------------|---|--|
| Indications For Use | The LSI Videoscopic Display System produces high quality video images for use in a wide range of medical applications, including surgery, microscopy and endoscopy. | The PVM-1343MD Color Video Monitor produces high quality video images for use in a wide range of medical applications, including surgery, microscopy, endoscopy and A/V. |
| Diagonal Picture Measure (in.) | 14 | 13 |
| Sterile Disposables | Plastic screen for placement in the surgical field. | None |
| Image Source | Texas Instruments Digital Micromirror Projector | SMPTE C (American standard phosphor) |
| Resolution | 800 (H) x 600 (V) active pixels | 2000 Characters (50 characters/line x 25 lines) >600 (H) TV lines |
| Video Input | 1.0V p-p, 75 ohms | 1.0V p-p, 75 ohms |
| Audio input | Phono jack | Phono jack |
| Power Requirements | 120V AC at 60 Hz 230V AC at 50 Hz | 110-130 V AC at 50-60 Hz |
| Power Consumption | 600 W (approx.) | 99W (approx.) |
| Dimensions (in.) | 8.04 (H) x 12.2 (W) x 16.38 (D) | 13.5 (H) x 13.63 (W) x 16.25 (D) |
| Weight (lb.) | 28.5 | 36.4 |

Summary:

The LSI Videoscopic Display System is a safe and effective device which is equivalent to the Sony Color Video Monitor (PVM-1343MD). The LSI Videoscopic Display System has a slightly larger screen when measured diagonally with 800 horizontal lines of resolution versus 600 horizontal lines of resolution for the Sony device. In addition the LSI Videoscopic Display System projects the video image into the surgical field, on a sterile screen, where it may be more easily viewed by the surgeon and others.