K973965

SMARTLIGHT

October 12, 1997

510(k) Summary

DEC 12 1997

Classification Name: Radiographic film illuminator

Model name: Smart Motorized Viewer SL8000^{DLX}

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 SL8000^{DLX} is a motorized radiographic film illuminator which enables electro-optical masking of the back illumination in such a way that those parts of the face plate which are covered by films are illuminated, and exposed parts of the face plate are masked (dark). The SL8000^{DLX} is designed to minimize problems which are associated with glare induced degradation of visual perception capacity and fatigue of film readers.

The SL8000^{DLX} is comprised of a motorized belt assembly, fluorescent backlight assembly, electro-optical shutter asembly, CCD based film detection assembly and PC-based control hardware and software.

Predicate devices include AMS/Planilux Rotolux and Mammolux (K922079), S&S/RADX MV220/MV400 and SmartLight's Digital Film Viewer SL4000^{PLUS} (K952188). The indication for use of the predicate devices and the SL8000 ^{DLX} is radiographic film reading.

The SL8000^{DLX} restricts the back illumination to film areas by electro-optical shutters in a similar way to SmartLight's Digital Film Viewer SL4000^{PLUS} (K952188). AMS/Planilux Rotolux and Mammolux (K922079) and S&S/RADX MV220/MV400 restrict the back illumination by manual adjustment of mechanical shutters.

The SL8000 ^{DLX} is designed to comply with MDD93/42/EEC standards of electrical and mechanical safety.

The only identified specific modality hazard is a failure in the electro-optical masking, which might degrade the quality of the film reading. Such failure is, however, immediately observed by the operator of the device, who should take the necessary steps (such as pressing the RESET key) to correct the problem.

Based on the above, it is SmartLight's opinion that the SL8000^{DLX} is substantially equivalent to the predicate devices.

Dan Ben-Zeev
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 1997

Dan Ben-Zeev
President
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Re: K973965
Smart Motorized Viewer SL8000^{DLX}
Dated: October 12, 1997
Received: October 17, 1997
Regulatory Class: I
21 CFR 892.1890/Procode: 90 IXC

Dear Mr. Ben-Zeev:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: Smart Motorized Viewer

Indications For Use:

Radiographic Film Reading

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K973965

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)