Appendix D 510(k) Summary for SmartLight Digital Film Viewer K991302

1. Sponsor

SmartLight Inc.
241 Main Street
Hackensack, NJ 07601
201-487-4544 (T)
201-487-4746 (F)

Contact: A. Robert Sohval, PhD

Date Prepared: April 15, 1999

2. Device Name

Proprietary Name: SmartLight Digital Film Viewer System
Common or Usual Name: Radiographic Film Illuminator
Classification Name: Radiographic Film Illuminator

3. Predicate Device

Product: ADViewer
Company: ADP Ltd.
K952188

4. Device Description

The Digital Film Viewer is a radiographic film illuminator designed to automatically adapt film-viewing conditions to compensate for known physical and psychophysical limitations in human visual perception when reading radiographic films.

The device senses the size, location, and density of films mounted on its faceplate and automatically adapts film-viewing conditions, as described below:

(a) Adaptive Light Intensity – The device automatically adapts the intensity of the back illumination system according to film density. Back light intensity ranges from 500-10,000 nits.

(b) Masking – The device enables electro-optical collimation of the back illumination such that those parts of the faceplate covered by films are illuminated, while the rest of the faceplate remains dark, eliminating extraneous glare.

(c) Film Scatter Suppression – The device incorporates an optical grid, which projects light in the forward direction to suppress optical scatter within the film (Callier effect).

(d) Ambient Light – The device reduces the ambient light level when films are mounted on its faceplate.

(e) Pupil Diameter – The device emits a dark blue light from its faceplate to control pupil dilation.

5. Intended Use

The Digital Film Viewer is a radiographic film illuminator with the following new indications for use:

(a) The Digital Film Viewer substantially improves the ability to detect and discern radiographic objects recorded on film compared to unmasked and masked light boxes.

(b) The Digital Film Viewer substantially improves the ability to detect and discern clinical information recorded on radiographic film compared to unmasked and masked light boxes.

(c) The Digital Film Viewer mitigates the age-dependent degradation in the ability to detect or discern radiographic objects recorded on film for readers over 30 years of age, as experienced on unmasked and masked light boxes.

6. Technological Characteristics and Substantial Equivalence

There are no significant differences in the technological characteristics of the Digital Film Viewer with the new indications for use and the predicate device. Both devices have the same overall intended use and function for the illumination and viewing of radiographic films.

7. Performance Characteristics

The new indications for use relate to device performance and are based on data from a controlled, statistical study of a large number of observers.

The study data demonstrate substantial and significant improvement in observer ability to detect and discern radiographic information recorded on film, when using the Digital Film Viewer compared to either an unmasked or masked light box.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 1999

A. Robert Sohval, Ph.D.
Chief Executive Officer
SmartLight, Incorporated
241 Main Street
Hackensack, New Jersey 07601

Re: K991302
SmartLight Digital Film Viewer,
Models SL 4000Plus and SL 2000 Plus
Dated: April 15, 1999
Received: April 16, 1999
Regulatory Class: I
21 CFR 892.1890/Procode: 90 IXC

Dear Dr. Sohval:

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 legally marketed predicate 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 requirements, 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE STATEMENT

510(k) Number: K991302

Device Name: SmartLight Digital Film Viewer System

Indications for Use: The SmartLight Digital Film Viewer System is a radiographic film illuminator designed to automatically adapt film-viewing conditions to compensate for known physical and psychophysical limitations in human visual perception when reading radiographic films.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991302

Prescription Use ✓
(Per 21 CFR 801.109)