K013880
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DEC 0 7 2001

510(k) Summary
for
Designs for Vision, Inc.
Daylite Light Sources

1. SPONSOR

Designs for Vision, Inc.
760 Koehler Avenue
Ronkonkoma, NY 11779

Contact Person: Amy Grumet-Avallone
Telephone: (631) 585-3300

Date Prepared: November 1, 2001

2. DEVICE NAME

Proprietary Name: Daylite XeNon Light Sources
Common/Usual Name: Surgical Lights
Classification Name: Surgical Lights/Routine Fiberoptic Lights

3. PREDICATE DEVICES

Walter Lorenz Surgical Inc. Lumenon Xenon Light Source	K992050
Welch Allyn, Inc. Xenon 300 Light Source	K980281

4. DEVICE DESCRIPTION

The Daylite XeNon Light Sources are comprised of high intensity xenon light sources, fiberoptic cables and fiberoptic headsets. The Designs for Vision Daylite Light Sources are supplied with headsets that were first placed into service prior to 1976 and are preamendment devices. The Designs for Vision headsets have been marketed since the early 1970's with a long history of safe use in the surgical suite. The headsets are either coaxial, bifurcated, or focusable designs.

The light source includes a universal chuck for fiberoptic cable attachment. The universal chuck accepts various sizes of light cables. The XeNon Light sources provide either 180-watt or 300-watt power output and contain a continuous illumination level adjustment which provides 6000°K color temperature light.

5. INTENDED USE

The Designs for Vision Daylite Light Sources are indicated for use in surgery and medical applications where high intensity illumination is required.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Daylite Xenon Light Source devices have the same intended use as the predicate device and similar technological characteristics. They all consist of Xenon Light Sources supplying fiberoptic illuminators with illumination for headlights.

7. PERFORMANCE TESTING

Testing has been performed which demonstrates the electrical safety characteristics of the Designs for Vision, Inc. Daylite XeNon Light Sources.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 7 2001

Designs for Vision, Inc.
c/o Mr. Donald James Sherratt
Medical Stream Director
Intertek Testing Services NA, Inc.
70 Codman Hill Road
BOXBOROUGH MA 01719

Re: K013880
Trade/Device Name: DayLite XeNon Light Sources
Regulation Number: 21 CFR §876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Codes: 78 GCT
Dated: November 21, 2001
Received: November 23, 2001

Dear Mr. Sherratt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013880

Device Name: Designs for Vision, Inc. Daylite XeNon Light Sources

Indications For Use:

The Daylite Xenon Light Source is indicated for use in surgery and medical applications where high intensity illumination is required

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013880

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

(Optional Format 1-2-96)