K051786/S

AUG 15 2005

Special 510(k) Summary
For
Designs for Vision, Inc.
Designs for Vision Melide Fiberoptic Light

1. SPONSOR

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

Contact Person: Ken Bragança
Telephone: (631) 585-3300

Date Prepared: June 29, 2005

2. DEVICE NAME

Proprietary Name: Melide Fiberoptic Light
Common/Usual Name: Surgical Lights
Classification Name: Surgical lamp

3. PREDICATE DEVICES

- Designs for Vision Fiberoptic Light K032283
- Cuda Products Corporation M300 Light Source K981962

4. DEVICE DESCRIPTION

The Designs for Vision Melide Fiberoptic Light (Melide Fiberoptic Light) is a modification of other legally marketed Designs for Vision surgical headlight systems. The Melide Fiberoptic Light consists of a lamp mounted in a chassis that also holds the AC power supply, dimmer for light intensity control, and a 530 nm filter. Light is passed through a fiberoptic cable to a set of optics in the headlight. The Melide Fiberoptic Light is compatible with all of the headsets available for use with the Designs for Vision surgical headlight systems described in K032283.

5. INTENDED USE

The Designs for Vision Melide Fiberoptic Light is indicated for use in surgery and medical applications where high intensity illumination is required.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The only modification made to the parent Designs for Vision Fiberoptic Light to produce the proposed Melide Fiberoptic Light is the type of lamp used as a light source. The parent Designs for Vision Fiberoptic Light was supplied with a tungsten halogen bulb that gave the light an intensity range of 0 – 2700 foot candles (±5%). The modified Melide Fiberoptic Light uses a metal halide bulb that provides an intensity range of 0-8000 foot candles (±5%). The Cuda Products M300 Light Source is also supplied with a metal halide bulb.

7. PERFORMANCE TESTING

Performance testing was conducted that confirms the safety and effectiveness of the modified Melide Fiberoptic Light for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2005

Designs For Vision, Inc.
c/o Ms. Cynthia J.M. Nolte, Ph.D.
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, Massachusetts 02760-4153

Re: K051786
Trade/Device Name: Designs for Vision Melide Fiberoptic Light
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FST
Dated: August 4, 2005
Received: August 8, 2005

Dear Dr. Nolte:

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 such 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 Section 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 (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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,

Barbara Buchs

for

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

Device Name: Designs for Vision Melide Fiberoptic Light

Indications for Use:

The Designs for Vision Melide Fiberoptic Light is indicated for use in surgery and medical applications where high intensity illumination is required.

Prescription Use ___X___ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

K051786 Barbara Bucheit for Melberson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051786