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Summary of Safety Information | **MEDICAL VISION INDUSTRIES, INC.**
Section 21(b), Premarket Notification | **SEPTEMBER 3, 2004**

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:**
LitePort® LP100 Surgical Illuminator

Common Name(s):
Surgical light
Illumination device

Classification Name(s):
Surgical Lamp

2. **Establishment Information/Owner Operator ID:**
Name: **Medical Vision Industries, Inc.**

Owner/Op.
ID Number: Pending

Address: 2209 Warmsprings Rd.
Modesto, CA 95356
(800) 408-0046
(707) 769-7974

3. **Classification(s):**
Sec. 878.4580 Surgical lamp.

(a) Identification. A surgical lamp (including a fixture) is a device intended to be used to provide visible illumination of the surgical field or the patient.

(b) Classification. Class II.

Classification Panel: General and Plastic Surgery Devices Panel

Product Code(s): FTF

4. **Performance Standards**
Food and Drug Administration mandated Performance standards are not in effect. The ***LitePort® LP100 Surgical Illuminator*** complies with voluntary Performance Standards applicable to all existing surgical lamps.

5. **Special Controls:**
As a Class II medical device, the ***LitePort® LP100 Surgical Illuminator*** is subject to the Special Controls requirement. At the present time we are not aware of Special Controls designed and intended to specifically cover surgical illumination equipment. Identifiable controls of a general nature are as follows:

(i) Compliance with design specifications,
(ii) Compliance with specified labeling requirements.

6. ***Summary Basis for Equivalence:***
The device is demonstrated substantially equivalent based on illumination technology, functional parameters, materials, indications for use, electrical safety, performance testing and sterility validation. All testing is conducted in accordance with appropriate ISO/EN test protocols.

7. **Legally Marketed Comparison Device:**
Medical Vision Industries, Inc. believes that the ***LitePort® LP100 Surgical Illuminator*** is substantially equivalent to the following device system identified earlier and marketed by Suncoast Medical Manufacturers:

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Suncoast Medical Manufacturers, Inc. Flexible Illuminator; K840371, K840372, K840373

The Suncoast device is cleared for marketing, having met the requirements for a finding of substantial equivalence on March 24th, 1984. The comparison device contains an illuminator and accessories system that performs substantially the same function as the proposed ***LitePort® LP100 Surgical Illuminator***. Equivalence can be seen in the basic design, materials, intended use and performance characteristics. Particular reference should be made to the fact that the both the Suncoast device and the ***LitePort® LP100 Surgical Illuminator*** are designed to provide illumination to deep abdominal or thoracic surgical procedures via the use of trochar or tube.

8. ***Description of the Device:***
The ***LitePort® LP100*** illumination device is a tubular fully self contained, sterile, disposable surgical illuminator powered by batteries.

Intended Use. Supplemental surgical illumination within the thoracic and abdominal cavity.

Summary of Non-Clinical testing:
The Liteport surgical illumination units were tested for performance illumination levels and duration of useful light levels. Additionally, sterility and packaging validation studies are designed to assure the device meets its design specifications. The devices perform according to predetermined performance requirements, providing evidence of their ability to operate within their specified environment. Product performance specifications were validated using an appropriate methodology.

9. **Company Contact:**
Mr. Chris A. Wolff
(800) 408-0046
(707) 769-7974

10. **Submission Correspondent:**
Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C -100
Pleasant Hill, CA 94523-3389
925.356.2640 - 925.356.2654 - fax

11. **Manufacturing Facility:**
The devices are manufactured under contract at the following address:
2209 Warmsprings Rd.
Modesto, CA 95356
(800) 408-0046
(707) 769-7974

The devices are manufactured by Medical Vision Industries, Inc. and are shipped for sale or distribution in the U.S.A and elsewhere.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 13 2004

Medical Vision Industries, Inc.
c/o Mr. David W. Schlerf
Buckman Company, Inc.
200 Gregory Lane, Suite C-100
Pleasant Hill, California 94523

Re: K041621
Trade/Device Name: LitePort® LP100 Surgical Illuminator
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical Lamp
Regulatory Class: II
Product Code: FTF
Dated: March 31, 2004
Received: June 16, 2004

Dear Mr. Schlerf:

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 (301) 594-4659. 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number : K041621

Device Name(s): ***LITEPORT® LP100 SURGICAL ILLUMINATOR***

Intended Use Statement(s):

The ***LitePort®*** LP100 Surgical Illuminator provides supplemental illumination in surgical procedures in the thoracic and abdominal cavities.

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)

Miriam C. Provost

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

510(k) Number K041621