MAY - 5 2004

510(k) SUMMARY

K040294

PhotoMedex, Inc.
LaserPro 810, 940 and 980 Systems Dioxide Laser Systems

1. GENERAL

- *Submitter:* PhotoMedex, Inc.
  147 Keystone Drive
  Montgomeryville, PA, 18936
- *Contact Person:* Bob Rose
- *Date Prepared:* February 2, 2004

2. DEVICE NAME

- *Classification name:* Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
- *Common or usual name:* Diode laser
- *Trade or proprietary name:* LaserPro Diode Surgical Laser System

3. PREDICATE DEVICES

Diode Surgical Laser Systems

- **Diomed D15 & D30 Laser Systems (K023543)**
- **Premier Aurora Laser System (K954316)**
- **SLT Thermalite 810, 940 & 980 Laser Systems (K952661)**

4. DEVICE DESCRIPTION

The PhotoMedex LaserPro 810. 940 and 980 Diode Laser Systems are designed to provide laser power at wavelengths of 810nm, 940nm, and 980nm, depending on model, which can be used for the procedures indicated in the next section of this summary . The system is comprised of the following main components:

- A laser console/cabinet with fiber port to accept SMA-905 connectors.
- Display panel with soft-touch keypad control and separate Emergency Off button.
- Laser system microprocessor control electronics with operating software
- A detachable covered footswitch.

5. INDICATIONS FOR USE

The PhotoMedex LaserPro 810. 940 and 980 Diode Laser Systems (and the fiber delivery systems and accessories that are used with them to deliver laser energy) are indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic (dermatology and plastic surgery), gastroenterology, general surgery, genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), ophthalmology, orthopedics, podiatry, pulmonology, and thoracic surgery.

6. SUBSTANTIAL EQUIVALENCE

The PhotoMedex LaserPro 810. 940 and 980 Diode Laser Systems, when used in conjunction with cleared delivery accessories, share the same indications for use, similar design features, functional features, and therefore are substantially equivalent to the predicate devices which includes the Diomed D15 & D30 Laser Systems (K023543), the Premier Aurora Laser System (K954316), and the SLT Thermalite 810, 940 & 980 Laser Systems (K952661).

7. SAFETY AND EFECTIVENESS

The PhotoMedex LaserPro 810. 940 and 980 Diode Laser Systems are designed, tested and manufactured in accordance with both mandatory and voluntary Standards ensuring when used with marketed cleared delivery systems identified to be compatible, they are considered both safe and effective for the medical applications indicated. No new clinical indications are to be provided by the introduction of LaserPro Diode Surgical Lasers as compared to the identified predicates, which have previously demonstrated clinical effectiveness.

8. CONCLUSIONS

Based on the information reviewed and provided within this application, PhotoMedex believes that the LaserPro 810. 940 and 980 Diode Laser Systems are substantially equivalent to, and are safe and effective as the legally marketed identified predicate devices, the Diomed D15 & D30 Laser Systems (K023543), Premier Aurora Laser System (K954316), and the SLT Thermalite 810, 940 & 980 Laser Systems (K952661), in that they share the same mechanisms for laser energy delivery and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 5 2004

Mr. Bob Rose
Director of Regulatory Affairs
PhotoMedex, Inc.
147 Keystone Drive
Montgomeryville, Pennsylvania 18936

Re: K040294
Trade/Device Name: LaserPro® 810, 940, and 980 Surgical Diode Laser Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 5, 2004
Received: February 6, 2004

Dear Mr. Rose:

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

Indications for Use

510(k) Number (if known): K040294

Device Name: LaserPro® 810, 940 and 980 Surgical Diode Laser Systems

Intended Use/Indications For Use:

The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems, (and the fiber delivery systems and accessories used to deliver laser energy), are intended for delivery of laser light in the contact or non-contact mode during surgical procedures, including via endoscopes, introducers, or catheters. The PhotoMedex LaserPro 810, 940 and 980 Surgical Diode Laser Systems, (and the fiber delivery systems and accessories used to deliver laser energy), are generally indicated for use in surgical applications requiring the ablation, vaporization, excision, incision, hemostasis or coagulation of soft tissue in surgical procedures in medical specialties including: dermatology, gastroenterology, general surgery (including specific treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein), genitourinary surgery (urology), gynecology (GYN), neurosurgery, otolaryngology (ENT), orthopedics, ophthalmology, pulmonology, and thoracic surgery.

Miriam C. Provost

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

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

510(k) Number K040294

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

Concurrence of CDRH, Office of Device Evaluation (ODE)