510(k) Summary Statement.
ICN Photonics Ltd., Nlite System

1. General Information.

Submitter: ICN Photonics Ltd
Units 1 & 2 Heol Rhosyn
Dafen Parc,
Llanelli,
Carmarthenshire,
Wales,
UK, SA14 8QG

Contact : Ian Mortimer – Regulatory and Quality Manager.

Summary Preparation date : 28 Feb 2002

2. Names :

Device Name : Nlite System

Primary Classification Name : Laser Powered Surgical Instrument.

3. Predicate Devices :

K013043 – Candela Clearbeam Pulse Dye Laser System
K921842 – Cynosure. Photogenica V Pulsed Dye Laser.

4. Product Description

The NLite System is a flashlamp pumped, pulsed dye laser consisting of the following:

- Main laser console incorporating the laser resonator and external optics, high voltage delivery system, internal cooler, fluid circulation system, control unit and user interface;
- Flexible fibre optic delivery device and optical handpiece;
- Footswitch for pulsing control.

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5. Indications for Use

The NLite system is indicated for use in the specialties of Dermatology and Plastic Surgery applications, and in particular for the treatment of Vascular lesions, such as Port Wine Stains, Telangiectasia, Leg Veins, Spider Veins, Spider Naevus, Poikiloderma of civatte, Hemangiomas, Angiomas, Rosacea

And benign cutaneous lesion, such as: Scars, Straie, Psoriasis, Verrucae Vulgaris and Warts.

6. **Rationale for Substantial Equivalence**

The key laser parameters, namely wavelength, pulse duration, energy density and delivery mechanism, produced by the NLite System are equivalent to both the predicate devices. The specific indications for use for the NLite System are identical that of the predicate. There is an identical interaction in the specific targeting of the Vasculature within the dermal region of the skin. The predicate devices are intended to produce permanent damage to the vasculature as is the NLite System.

As far as technological considerations are concerned, the NLite System utilizes the same design principles as the predicate devices, namely the method of producing the laser output is identical. More specifically, the laser output parameters and delivery method are equivalent in nature to those provided by the predicate devices.

7. **Safety and Efficacy Information**

None required – The precise equivalence to predicate devices negate the need to support additional efficacy information.

8. **Conclusion**

The NLite System has been found to be substantially equivalent to the predicate devices, specifically in technological design resulting in identical desired physiological interactions. The design and manufacture of the device is in accordance with the relative international standards and the potential risk to operator and patient has been minimized.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ian Mortimer
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Dafen Parc
Llanelli,
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Wales
United Kingdom, SA14 8QG

JUN 0 4 2002

Re: K020729
Trade/Device Name: ICN Photonics Ltd. NLite System
Regulation Number: 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 28, 2002
Received: March 6, 2002

Dear Mr. Mortimer:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR 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,

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

Section 4
Indications for Use Statement as Requested by FDA

510(k) Number (if known): K020729

Device Name: ICN Photonics Ltd., NLite System

Indications for Use:

The NLite System laser system is indicated for use in Dermatological and Plastic Surgery applications and ***this device is intended for use in the treatment of Vascular lesions, such as :*** Port Wine Stains, Telangiectasia, Leg Veins, Spider Veins, Spider Naevus, Poikiloderma of civatte, Hemangiomas, Angiomas, Rosacea

And benign cutaneous lesion, such as: Scars, Straie, Psoriasis, Verrucae Vulgaris and Warts.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)
Concurrence of CDRH, Office of Device Evaluation (ODE)

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

for Mark N. Milano
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020729