510(k) Summary

Noveon™ (Model LS1100-01-0968) Dual Wavelength Laser Instrument

November 19, 2007

Submittal information:

Post-approval contact:
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Nomir Medical Technologies
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Device name and classification

510(k) Number: K071815
Proprietary Name: Noveon™ (Model LS1100-01-0968)
Common Name: Medical Diode Laser
Classification Name: Class IV Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Classification Panel: General and Plastic Surgery Devices
CFR Section: 21 CFR 870.4810
Class: II
Product Code: GEX

Predicate Devices

- Ceralas D 810 Diode Laser System, K032864, by Biolitec, Inc
- LaserPro 810, 940, and 980 Dioxide Laser Systems, K040294, by Photomedex, Inc
- Vectra Laser System, K060114, by Xintec Corporation
- BWF-5 Medical Laser Series, K062363, by B&W Tek Inc
- PhoTex15 Diode Laser Series: 980, 810, 940, K060304, by BioTex Inc
- Q YAG 5 Nd:YAG Laser System, K061436, by Palomar Medical Technologies, Inc
- Medlite C3 Q Switched Nd:YAG Laser, K011677, by Continuum Electro-Optics, Inc (now Hoya ConBio, Inc)

Device Description

The Noveon™ (Model LS1100-01-0968) is a Class IV Laser Surgical Instrument for use in General and Plastic Surgery and Dermatology. The device consists of the following components and accessories:

1. Laser Source and Control Unit: Two Class IV laser diodes, each providing continuous-wave laser light, one at the 870 nm and one at 930 nm wavelength. The power output of each laser is selectable from 1W to 8W in 0.1 W increments. There are two touch sensitive screens to control the optical power output of each laser and a separate emergency on/off button.
2. Foot Pedal Switch: turns the lasers on/off when the lasers are enabled.

3. Flexible Optical Fiber and End Piece: designed to be lightweight for holding the distal end of the fiber comfortably in the hand to perform procedures.

Intended Use
The Noveon™ (Model LS1100-01-0968) delivers continuous wave laser light in the contact or non-contact mode during surgical procedures of the skin, subcutaneous tissues and nasal passages in dermatology, plastic surgery, podiatry and otolaryngology. The device is indicated for use in applications requiring incision, excision, vaporization, hemostasis, or coagulation of soft tissue.

Performance Data
Performance Standards

- The Noveon™ (Model LS1100-01-0968) complies with applicable performance standards for light emitting products as outlined in 21 CFR 1040.10 and 21 CFR 1040.11.
- The device has been tested and verified by Intertek ETl Semko as conforming to 47 CFR Part 15, Subpart B Unintentional Radiator Class A. Prior to introduction into the US market, the device will be tested and verified to conform to the applicable voluntary electrical equipment standards; IEC 60601-1, IEC 60601-1-1, and IEC 60601-1-2.
- The device also conforms to the standards for biocompatibility as given by Cytoxicity: ISO 10993-5, Sensitization: ISO 10993-10, and Irritation: ISO 10993-10.

Performance Testing
A surgical study with a live Yorkshire pig was conducted to test the capability of the Noveon™ (Model LS1100-01-0968) to perform incision, contact coagulation, non-contact coagulation, debridement, curettage and excision. Results from this study demonstrate the device satisfactorily performed these procedures when used by a medical professional. Importantly, there were no adverse events that were noted during the performance of any of these demonstrations. Altogether there were 130 passes of the laser made during this demonstration, of which 127 were made in the contact mode: incision (5), contact coagulation (4), debridement (19), curettage (31), and excision (68).
Using tissue samples of porcine skin, muscle, and liver we tested individual samples with exposures to 940 nm, 930 nm, and 870 nm. In addition, we tested samples with 870 nm and 930 nm in three different optical power combinations. The testing included both contact and non-contact (free beam) mode. The testing was performed in triplicate. For each test the width and depth of the zone of ablation, the zone of coagulation (necrosis) and the zone of total destruction were recorded. These data substantiate that the difference in tissue effect was comparable to the 940 nm predicate device and any differences were not of clinical significance.

Substantial Equivalence
The Noveon™ (Model LS1100-01-0968) share the same indications for use, similar laser and electronics design features, safety and functional features, and therefore are substantially equivalent to the predicate devices listed above.

Safety and Effectiveness
The Noveon™ (Model LS1100-01-0968) is designed in accordance with both mandatory and voluntary Standards ensuring it is both safe and effective for the medical procedures indicated above. No new clinical indications are to be provided by the introduction of the device as compared to the predicate devices, identified above, which have previously demonstrated clinical effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 8 2007

Nomir Medical Technologies, Inc
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Newton, Massachusetts 02466

Re: K071815
Trade/Device Name: Noveon™ Model LS1100-01-0968
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 19, 2007
Received: November 20, 2007

Dear Mr.Burtt:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

I.1 Indications for Use Statement

510(k) Number (if known): K071815

Device Name: Noveon™ (Model LS1100-01-0968)

Indications For Use:

The Noveon™ (Model LS1100-01-0968) delivers continuous wave laser light in the contact or non-contact mode during surgical procedures of the skin, subcutaneous tissues and nasal passages in dermatology, plastic surgery, podiatry and otolaryngology. The device is indicated for use in applications requiring incision, excision, vaporization, hemostasis, or coagulation of soft tissue.

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

510(k) Number K071815

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)