K030652 1/2



# 510(k) Summary

JUL 17 2003

as required by section 807.92(c)

**Submitted by:**

ANDI electromedical ApS
Parallelvej 2, DK-4300 Holbek
Phone: 01145 5944 0832
Fax: 01145 5944 2911

**Contact Person:** Arne Grinsted

**Prepared On:** February 28, 2003

**Classification Name:** Lamp, Infrared

**Common Name:** Infrared Laser

**Proprietary Name:** POWER LASER 90

**Classification:** The device satisfies the 21 CFR definition of a Class II infrared lamp as follows:

| Regulation Number | Classification Number | Product Nomenclature | Identification / Classification |
|---|---|---|---|
| 890.5500 | ILY | Lamp, Infrared | A device that emits energy at infrared frequencies (approximately 700 nanometers) to 50,000 nanometers to provide topical heating |

**Establishment registration:** Owner / Operator No: 9052408

**US Representative:**

National Medical Alliance
12415 Old Meridian St.
Carmel, IN 46032
Tel: 800-662-7283
Contact person: Jeff Worrell

**Development:** ANDI electromedical ApS has developed the device.

**Production:** ANDI electromedical ApS is manufacturing and packaging the device.

**Reason for the 510(k):** The Product has never been marketed in USA before. However the POWER LASER range has been marketed in Europe since 1998. The product, which is for professional use, is used for therapy.

K030692 2/2



| | |
|---|---|
| **Substantial Equivalence:** | POWER LASER 90 is substantially equivalent to the Micro light 830, which was the subject of 510(k) number K010175. The POWER LASER 90 has the equivalent intended use (i.e. pain relief). |
| **Device Description:** | The POWER LASER 90 is a hand-held, battery operated, non-invasive, non-thermal, low energy, infrared laser, therapeutic medical device. A separate battery charger can recharge the battery when it is removed from the POWER LASER 90. POWER LASER 90 is a finished device, which is delivered packed with battery charger and complete labeling for the user. |
| **Special Controls:** | The POWER LASER 90 as well as the battery charger demonstrates compliance to relevant safety-standards, EMC standards and standards for laser equipment. |
| **Statement of Indications for use:** | The POWER LASER 90 is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2003

Mr. Arne Grinsted
President
ANDI electromedical Aps
Parallelvej 2,
DK-4300 Holbeck

Re: K030692
Trade/Device Name: Power Laser 90
Regulation Number: 21 CFR 890.5500
Regulation Name: Lamp, non-heating, for adjunctive use in pain therapy
Regulatory Class: II
Product Code: NHN
Dated: May 23, 2003
Received: May 27, 2003

Dear Mr. Grinsted:

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. 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) you may obtain. 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,

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 (if known): K030692

Device Name: POWER LASER 90

Indications For Use: The POWER LASER 90 is indicated for adjunctive use in the temporary relief of hand and wrist pain associated with Carpal Tunnel Syndrome.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Miriam C Provost

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

510(k) Number K030692