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MAR 25 2005

SUMMARY OF SAFETY AND EFFECTIVENESS

SUBMITTED BY: ELTECH s.r.l.
Via Castagnole, 20/H
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Italy
Phone: 0039 422 210 430 Fax: 0039 422 297 137

1. **DEVICE NAME (Trade/common, and classification):** Klaser Therapy Probe.

   Classification: Class II
   Regulation Nos.: 890.5500
   Product Codes: ILY

2. **PREDICATE DEVICES:**

   ALT Laser, Model VTR 75 – Cleared under K031613
   Vectra Genisys Laser System – Cleared under K 040662
   Solaris D890 – Cleared under K040729

3. **PERFORMANCE STANDARDS:** Klaser conforms to the applicable requirements of 21 CFR section 1010 (Performance Standards for Electronic Products: General) and 21 CFR sections 1040.10 and 1040.11 (Performance Standards for Light-Emitting Products).

4. **DESCRIPTION:** Klaser is an infrared therapy device, composed of emitter, software, probe for the delivery of light and an on/off button to activate and deactivate the infrared emission.

5 **INTENDED USE/ INDICATIONS FOR USE:** Klaser provides infrared therapy for the following allowed claims:

Infrared therapy to provide topical heating for:

- Temporary increase in local blood circulation
- Temporary relief of minor muscles and joint aches, pains and stiffness
- Relaxation of muscles
- Muscles spasms
- Minor pain and stiffness associated with arthritis

The intended Use/Indications For Use stated herein are identical to the cleared indications for the predictae device.

6. **SUBSTANTIAL EQUIVALENCE (SE) RATIONALE:** K-Laser generates infrared therapy for treatment of selected medicals conditions and shares the same or similar basic characteristics and the same intended use as the predicate device. Therefore, the proposed K-Laser is substantially equivalent to the Solaris D890, cleared under K040729; to ALT Laser Model VTR 75, cleared under K031612; to Vectra Genisys Laser System, cleared under K04066.

7. **SAFETY AND EFFECTIVENESS:** There are no substantive differences between the products defined in this 510(k) submission and the predicate device. They are similar to the technologies that are currently used in other similar medical devices. They were developed and documented under Eltech's mature Quality Managerment System, under The Quality System Regulation, 21 CFR Part 820, under design/change control, and verified/validated to applicable standards/guidance documents.
Besides, Eltech's Quality Assurance System is certified by CERMET, notified body n. CE 0476, according to Annex II of 93/42 EEC Directive, transposed in Italy by Dlgs. n. 46 of 24 February 1997.
Klaser is safe and effective when used as indicated in specific applications under a clinician's supervision/therapy program.

Signed: _____ Date: 12-7-2004

Eltech s.r.l.
Francesco Zanata
President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 25 2005

Eltech s.r.l.
c/o Mr. Richard Albright
Laser Therapy Products
1510 Towne Park Lane
Franklin, Tennessee 37067

Re: K050070
Trade/Device Name: Klaser
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: February 18, 2005
Received: February 22, 2005

Dear Mr. Albright:

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 (240) 276-0115. 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost

Miriam C. Provost, Ph.D.
Acting 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): K050070

Device Name: **KLASER**

Indications for Use:

The device is indicated for emitting energy in the Infrared Spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis and promoting relaxation of the muscle tissue and to temporarily increase local blood circulation.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K650070