DEC 1 1 2003

K031612
1 of 1

510(k) SUMMARY

The Summary of Safety and Effectiveness on the ALT Laser, Model VTR75 reflects data available and represented at the time the submission was prepared, but caution should be exercised in interpreting the data. The results of future studies and or tests may require alterations of the conclusions or recommendations set forth.

Applicant	Bruce R. Coren, DVM, MS 1209 North Flagler Drive West Palm Beach, Florida 33401
Telephone **Facsimile**	(561) 722 – 1153 (561) 659 – 0163
Date	August 22, 2003
Name	ALT Laser, Model VTR75
Classification	Infrared Lamp, 21 CFR 890.5500
Predicate:	BioScan, Inc., BioPack, K993685 market clearance date July 18, 2000.
Description	The system will produce a 980nm infrared and a 660 nm red visible laser light in overlapping patterns. The two types of light will be mixed such that the visible 660 nm light becomes a reasonable indicator of the invisible infrared 980nm light. The 660 nm visible aiming laser light will be sensed and if the light is absent, it will lock out the infrared 980nm light and alert the operator.
Intended Use	ALT Laser, Model VTR75 is intended to emit energy in the infrared spectrum to provide topical heating for use when heat is indicated in the temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis, and promoting relaxation of the muscle tissue.
Contraindications	• Do not apply infrared light to abdominal or lumbosacral points in pregnant females. • Do not apply infrared light to the epiphyseal lines in children. • Do not apply infrared light to the thorax or over the pacemaker itself in patients with pacemakers. • Do not apply infrared light over the thyroid gland, ovaries and testicles. • Do not apply infrared light to patients who are taking drugs that have heat or light sensitive contraindications, such as but not limited to certain types of steroids
Warning	• Do not use in the presence of flammable solvents or anesthetics. • Never look directly into the laser light source or at scattered laser light from any reflective surfaces. Never sight down the beam into the source. • Direct eye contact with the output beam from the laser will cause serious damage and possible blindness. • Avoid direct exposure to the laser light. The intensity of the beam can easily cause flesh burns or ignite clothing. • Never look directly into the beam or at a specular reflection even while wearing protective eyewear.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2003

Bruce R. Coren, DVM, MS
President
Avicenna Laser Technology, Inc.
1209 North Flagler Drive
West Palm Beach, Florida 33401

Re: K031612
Trade/Device Name: ALT Laser
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: November 21, 2003
Received: November 25, 2003

Dear Dr. Coren:

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

510(k) Number (if known): K031612

Device Name: ALT Laser

Indications For Use:

ALT Laser, Model VTR75 is intended to emit energy in the infrared spectrum to provide topical heating for use when heat is indicated in the temporary relief of minor muscle and joint pain, muscle spasm, pain and stiffness associated with arthritis, and promoting relaxation of the muscle tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF 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 K031612

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

(Optional Format 1-2-96)