JUL - 2 2002 K014208

510(k) PREMARKET NOTIFICATION SUMMARY
(per 21 CFR 807.92)

SSIR SYSTEM

I. Applicant:

Russian-American Technology Associates, Inc.
23667 Patterson Road
Robertsdale, AL 36567
USA

Key Contact: Floyd T. Neth, Ph. D.
President

Date Revised: June 30, 2002

II. Device Name

Proprietary Name:	SSIR System
Common / Usual Name:	Infrared Lamp
Classification Name:	Infrared Lamp (21 CFR 890.555)
Product Code:	ILY

III. Predicate Device

The SSIR System is substantially equivalent to other infrared lamps currently in commercial distribution such as the Photonic Stimulator manufactured by Bales Scientific, Inc., the Super Nova / Acubeam systems manufactured by Light Force Technology, Inc., Light Patch manufactured by BioScan, Inc., and Nu Photonics Pain Therapist system manufactured by Nu Photonics, Inc.

IV. Intended Use of the Device

The SSIR System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for:

- the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm;
- the temporary increase in local circulation; and / or
- the temporary relaxation of muscle.

V. Description of the Device

The SSIR System is a modern, safe, and easy-to-use devices, which provide continuous heat therapy. The SSIR System consists of a power supply that houses the electronics and controls and treatment module (Velcro Strap Model) that contain the infrared radiating element. The power supply is manufactured from a plastic material that is used in similar products currently in commercial

distribution by various medical device companies. The power supply houses a green LED light to indicate when the unit is active.

The Velcro Strap Model is a treatment module comprised of a silicon diode in a black anodized aluminum housing with attached velcro straps. The area of this module that comes in contact with the treatment site is covered with black cotton felt.

VI. Summary of the technical characteristics of the SSIR System to the referenced predicate devices.

The SSIR System and the aforementioned predicate devices are infrared lamps as defined in 21 CFR 890.5500. The device utilizes infrared diodes to generate topical heating for the purpose of elevating tissue temperatures for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local circulation and the temporary relaxation of muscle. The System is intended to be placed directly on the skin to provide heating.

VII. Testing

Testing of the SSIR System included functional performance testing and electrical safety testing.

VIII. Conclusions

Pursuant to the testing and comparison to the predicate devices, the SSIR System has the same intended uses, with similar functional and performance characteristics. The SSIR System is designed to comply with the generally accepted therapeutic heat performance specifications by producing a level of tissue temperature reported in literature[1] and accepted by the Federal Food and Drug Administration.

The SSIR System performs as intended and does not raise any new safety or efficacy issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2002

Russian-American Technology Association, Inc.
c/o Ms. M. Joyce Heinrich
Regulatory Consultant
Texas Applied Biomedical Services
8303 S.W. Freeway, Suite 835
Houston, Texas 77074-1601

Re: K014208
Trade/Device Name: SSIR System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: April 18, 2002
Received: April 19, 2002

Dear Ms. Heinrich:

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,

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

Statement of Indications for use

510(k) Number (if known): K014208

Device Name: **SSIR System**

Indications for Use:

The SSIR System is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for:

- the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm;
- the temporary increase in local circulation; and / or
- the temporary relaxation of muscle.

(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) **(Optional Format 1-2-96)**

(Division Sign-Off)

510(k) Number K014208

023