



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Varaya Photochemicals, LLC
Mr. Myk Lum
Co-owner
16511 Scientific Way, Suite 200
Irvine, California 92618

December 8, 2015

Re: K150716
Trade/Device Name: Varaya Sport (Model 200)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: October 20, 2015
Received: November 2, 2015

Dear Mr. Lum,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Joshua C. Nipper -S

Binita S. Ashar, M.D., M.B.A., F.A.C.S.

For Director

Division of Surgical Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K150716

Device Name
Varaya Sport Model 200

Indications for Use (Describe)

The Varaya Sport Mode 200 is indicated/intended for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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VARAYA PHOTOCEUTICALS, LLC
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varaya
photoceuticals

510(k) Summary of Safety and Effectiveness

This traditional 510(k) summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Owner's Name: Varaya Photoceuticals, LLC
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510(k) preparation date: March 11, 2015

Device Name and Classification:

Trade and Proprietary name: Varaya Sport (Model 200)
Common Name: Infrared Lamp
Classification Name: Lamp Infrared, Therapeutic Heating
Product Code: ILY
Regulation Number: 21 CFR 890.5500
Class: II

Predicate Device:

The legally marketed predicate for the Varaya Sport (Model 200) is: **K112494**, Varaya Sport (Model 200).

Device Description:

The Varaya Sport (Model 200) is a therapeutic device utilizing high-powered Light Emitting Diodes (LEDs) to distribute specific wavelengths of light energy. The LEDs in the device are: one visible Red (660nm) and one invisible nearInfrared (850nm). The device is handheld .25" above the desired treatment area and operates when connected to an electrical outlet. The device has an on/off button and control panel for a built-in timer and wavelengths. The device

has integrated optics to ensure uniform distribution of light energy. The device comes with goggles for safety and a power cord/adaptor. Recommended treatment time is 10-15 minutes per use.

Intended Use:

The Varaya Sport Model 200 is indicated/intended for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm; promoting the relaxation of muscle tissue; and to temporarily increase local blood circulation where applied.

Technological Characteristics:

This submitted device is the same device as in K112494 (predicate) with no technological changes. The Varaya Sport (Model 200) device utilizes two high-powered LEDs: one Red and one nearInfrared in a handheld unit. The device is held .25" above the desired treatment area and operated when connected to an electrical outlet. The device has an on/off button and control panel for a built-in timer and wavelengths. The device has integrated optics to ensure uniform distribution of light energy. The device comes with goggles for safety and a power cord/adaptor.

Nonclinical and Clinical Testing:

The subject device has been tested to confirm compliance in accordance with IEC 60601-1 (2nd Edition), IEC 60601-1-2 and ISO 10993 standards. The subject device has been tested to confirm compliance per FDA required tissue temperature heating requirement. The subject software has been fully validated per FDA requirement for software validation. These test results serve to confirm that the Varaya Sport (Model 200) does not raise any new issues of safety or effectiveness.

Over-the Counter Use Study:

Varaya Photoceuticals, LLC has performed the OTC Use Study (self-selection, usability and label comprehension) to ensure the understanding of the proper use as well as any risks of misuse of the Varaya Sport (Model 200) as an over-the-counter medical device product. Study participants were recruited solely from the general population, not specifically from a group of intended consumers. This was done to ensure an unbiased, naive sample representative of the general US population. The study data shows that the device design essentially mitigates anticipated risks of misuse and misunderstanding of the instruction for use. The self-selection protocol and results confirmed a person was able to appropriately self-select themselves into using or rejecting the device.

End of 510(k) Summary