K073681

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

1. Applicant

DEC 0 9 2008

DavaRay Inc.
2232 S. Main St. #422
Ann Arbor, MI 48103

Contact Person: David J. Arndt, President DavaRay, Inc.
Phone Number: (734) 276-5366
Fax Number: (734) 677-7791
Email: davidjarndt@sbcglobal.net

2. Device Name

Nanobeam 940

3. Predicate Device

The Nanobeam 940 is similar to the BioBeam 940 (K042813), the MedLight 630 Pro (K042813) and the LumiWave 1X4 (K051816). We consider the Nanobeam-940 to be substantially equivalent to these three devices which were approved for market through the 510(k) exemption process.

4. Intended Use of the Device

The indicated use of the Nanobeam 940 is to emit energy in the Near-IR spectrum for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

5. Description of the Device

DavaRay's Nanobeam 940 is a near-infrared light device used for therapeutic purposes. The proposed classification for the new device is Class II. The Nanobeam 940 falls within the definition of a "Sec. 890.5500 Infrared Lamp" Class II device.

Thank you for your review of our application,

David J. Arndt

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DavaRay, Inc.
% Mr. David J. Ardnt
President
2232 S. Main Street, #422
Ann Arbor, Michigan 48103

DEC 0 9 2008

Re: K073681
Trade/Device Name: Nanobeam 940
Regulation Number: 21 CFR 890.5550
Regulation Name: Infared Lamp
Regulatory Class: II
Product Code: ILY
Dated: November 19, 2008
Received: November 24, 2008

Dear Mr. Ardnt:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K073681/S001
Device Name: Nanobeam 940

Indications for Use:

The indicated use of the Nanobeam 940 is to emit energy in the Near-IR spectrum for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)
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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073681