DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

January 5, 2017

Vevazz, LLC
Mr. Jamie Fettig, DC
Owner
30520 Rancho California Rd, Suite 107-46
Temecula, California 92591

Re: K162763
Trade/Device Name: Vevazz Led Heat Lamp
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: ILY
Dated: November 3, 2016
Received: November 8, 2016

Dear Dr. Fettig:

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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
162763

Device Name
Vevazz LED Heat Lamp

Indications for Use *(Describe)*
The Vevazz is a device that emits energy in the infrared spectrum and is to be used to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain, arthritis, stiffness or muscle spasms; the temporary increasing of local blood circulation and/or the temporary relaxation of muscle.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510-(k) Summary

1. Submitters Information

Name: Vevazz, LLC
30520 Rancho California Road Suite 107-46
Temecula, CA 92591
Tel: 773-665-4005
Contact: Jamie Fettig, Owner
773-620-9500
jamie@healthyhuman.org

2. Date Prepared:

January 3, 2017

3. Device Name and Classification

Device	Vevazz LED Heat Lamp
Trade Name	Vevazz LED Heat Lamp
Regulation Description	Infrared lamp
Regulation Number	21 CFR 890.5500
Device Class	II
Review Panel	Physical Medicine
Product Code	ILY

4. Intended Use

The Vevazz is a device intended to emit energy in the visible and near-IR spectrum to provide topical heating for the purpose of elevating tissue temperature for a temporary relief of minor muscular and joint pain and stiffness, minor arthritis pain or muscle spasm; the temporary increase in local blood circulation and temporary relaxation of muscles.

5. Device Description

The Vevazz device is a moderately complex device that consists of a base unit that plugs into 120 VAC or 240 VAC main power with Ground (earth) and a 2 amp 250 VAC Fuse. The base unit can support up to 16 large LED paddles and 4 small LED paddles. The connections on the base are female phono jacks that are low voltage having a maximum electrical output of 16 VDC @ .5 amps for a total of 8 Watts per port. The large paddles consist of 28 LEDs in a series/parallel electrical connection that has a cord with a male phono jack. Small paddles consist of 4 LEDs and have matching electrical characteristics as the large paddles. Each LED produces 50 mw/cm2 of light energy with a wavelength of 650 nm; +/- 25 nm uniformly over the treatment area without producing hot spots.

6. Predicate Devices

- HVR Infrared Lamp by HVR, LLC - K101716
- Tanda Restore by Pharos Life Corporation - K090008
- HEATLUX by Home Skinnovations, LTD. - K120582

7. Technical and Performance Substantial Equivalency

The submission and predicate devices are fully compliant with USFDA recognized standards for electrical safety and emit a substantially equivalent amount of power and energy. Differences where they occur are minor and do not represent any risk or hazard.

Performance Characteristic	Vevazz	HVR Lamp	Tanda Restore	HeatLux
Power	50 mW/cm2	50-80 mW/cm2	60 mW/cm2	60 mW/cm2
Wavelength	650 nm +/- 25nm	650 nm to 950 nm	870 nm	645 nm
Waveform	Constant	Constant	Constant	Constant
Energy Source	LED	LED	LED	LED
Treatment Area	7.5 cm2	1000 mm2 (10 cm2)	27 cm2	7 cm2
Treatment Time	17 minutes (default)	90 seconds	3 minutes	3-5 minutes
Target Skin Temperature	41º±2ºC	42º±3ºC	41º±2ºC	41º±2ºC
Patient Contact Material	Rigid ABS	Rigid ABS	Rigid ABS	Rigid ABS

8. Bench Testing Summary

The Vevazz is in compliance with the following standards:

- IEC 60601-1:2005 +C1:2006, +C2:2007, AM1:2012, Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-57:2011, Medical electrical equipment – Part 2-57: Particular requirements for basic safety and essential performance of non-laser lightsource equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
- IEC 62471 Ed. 1, International Standard for Photobiological Safety for Lamps and Lamp Systems – General Requirements

- IEC 60601-1-2:2007, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests.

9. Clinical Testing Summary

The Vevazz heat performance was tested to verify it will reach an idle temperature of 40ºC and will maintain that temperature throughout the treatment for a minimum duration of 10 minutes ±2ºC. An IR camera was used to monitor skin temperature and uniformity on the abdominal region and multiple skin types.

10. Conclusion

The Vevazz is substantially equivalent to its predicate devices. Based on the technological comparison between the Vevazz and the predicates plus the human test data, it can be concluded that the Vevazz is equivalent to the identified predicates.