



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 24, 2014

Zimmer MedizinSysteme GmbH
% Ms. Kirsten Langen
Tuv Sud America Incorporated
1775 Old Highway, 8 North West
New Brighton, Minnesota 55112

Re: K141564
Trade/Device Name: OptonPro
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: ILY
Dated: September 10, 2014
Received: September 29, 2014

Dear Ms. Langen:

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" (21CFR 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,

David Krause -S

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

Indications for Use

510(k) Number (if known)

K141564

Device Name

OptonPro

Indications for Use (Describe)

- temporary relief of minor muscle and joint aches, pains and stiffness
- temporary relief of muscle spasm
- temporary relief of minor pain and stiffness associated with arthritis
- promoting relaxation of the muscle tissue
- temporary increase in local blood circulation

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”

5. 510(k) Summary

The following information is provided as required in 21CFR807.87 and the "Guidance Document for Heating and Cooling Devices 510(k)s".

a.) General

510(k) Submitter: Zimmer MedizinSysteme GmbH
Junkersstrasse 9
D-89231 Neu-Ulm
Germany

Contact person: Mr. Armin Petraschka
Project Manager
Phone: +49-731-9761-140
Fax: +49-731-9761-4475
E-mail: a.petraschka@zimmer.de

**Establishment
Registration:** 8010720

Submission Date: April 25th, 2014

Device Names:
Device Name: *OptonPro*
Trade Names: *OptonPro*
Common Names: Heating and Cooling Devices

**Regulation Numbers
and Classification
Names:** 21 CFR 890.5500 – Infrared Lamp

Classification: Class II

Product Codes: ILY

Panel: 89 – Physical Medicine

b.) Predicate Devices

	1.	2.
Device	K-1200	Vectra Genisys Laser System
Manufacturer	ELTECH s.r.l Via Castagnole, 20/H 31100 Treviso, Italy	CHATTANOOGA GROUP (Encore Medical) 4717 Adams Road. P.O. Box 489 Hixson, Tennessee 37343-0489
510(k) number	K091497	K040662

c.) Device Description

OptonPro is a topical heat lamp with laser light. It emits energy in the infrared spectrum to provide topical heating for the purpose of elevating the tissue temperature.

The OptonPro contains a Class IV laser unit with four simultaneously operating diodes with wavelengths of 810nm and 980nm transmitting their energy to an applicator through a flexible fibre optic cable. The applicator has an output spot size of 10 mm.

The optimum ration of absorption and penetration depth guarantees efficient stimulation of tissue and pain receptors. The treatment effect of the OptonPro is achieved with 980nm and 810nm. Additionally the OptonPro contains an aiming beam with 650nm.

Skin type, indication and desired depth of treatment define the operating mode and the required energy. Two operating modes are possible: continuous wave and serial pulse. The duty cycle can be adapted additionally (1:1 – 1:10). Patient feedback and direct access to the treatment parameters enable to adjust the application for individual requirements and to achieve treatment times of a few minutes.

The OptonPro includes comprehensive safety features. In addition to multi-step activation of the laser by the software, with software security key lock and footswitch for starting treatment, protective glasses, an emergency off switch and a hardware interlock are included in the system. The performance of the laser unit can be tested with an integrated power control unit. A thermal threshold test offers a tool to assess the warmth sensitivity and the individual local absorption rate. Additionally the user is assisted with a special reminder function for a delivered particular amount of energy.

OptonPro is an intuitive therapy system with touch screen and menu-guided operation. The maximum output power is 7 W. The adjustable output power corresponds with the chosen duty cycle. The OptonPro has a large colour display with 12 inch. A SD card is used as a memory, as a logbook and for updates.

Individual adjustments can be made at any time and saved for easy access. A program menu with 3 fixed programs and a favourites and memory menu with 120 memory slots for custom programs collects the most common settings and shows them when the OptonPro is started if required.

d.) Statement of indications for use

The indications for use of the proposed device are the same as those for the predicate devices:

- temporary relief of minor muscle and joint aches, pains, and stiffness
- temporary relief of muscle spasm
- temporary relief of minor pain and stiffness associated with arthritis
- promoting relaxation of the muscle tissue
- temporary increase of local blood circulation

e.) Comparison of Technological Characteristics

No	Feature	OptonPro	K-1200	Vectra Genisys Laser System
1.	power source	100 – 240 VAC, 50 / 60Hz	100 - 240 VAC, 47 - 63 Hz	120-240VAC, 50 / 60Hz
2.	battery powered	-	+	+
3.	dimensions (h x w x d) [cm]	30 x 35 x 20 (11.81 x 13.78 x 7.87 in)	19 x 18 x 20 (7.5 x 7 x 8 in)	16.3 x 28.8 x 32.8 (6.4 x 11.3 x 12.9 in)
4.	weight [kg]	3.8 (8.38 lb)	1.3 (2.9 lb)	2.3 (5.07 lb)
5.	housing materials	plastic	plastic	plastic
6.	laser class	4	4	3B
7.	applied part	B	B	B
8.	protection class	II	II	II
9.	laser system	laser diodes, fibre-optical cable	laser diodes, fibre-optical cable	laser diodes
10.	software control	+	+	+
11.	compliance with voluntary standards	Yes, -IEC/EN 60601-1 -IEC/EN 60601-1-2 -IEC 60601-2-22 -IEC 60825-1	Yes, -IEC/EN 60601-1 -IEC 60825-1	Yes, -IEC/UL/EN 60601-1 -IEC/UL/EN 60601-1-2 -IEC/UL/EN 60601-2-22 -IEC 60825-1 -21CFR 1040.10 & 1040.11 -CAN/CSA C22.2 No.601.1- M90 w/A2
12.	prescription use	+	+	+
13.	intended use	emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature heating for the following indications for use:	emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature heating for the following indications for use:	indicated for topical heating for the following indications for use:
14.	indications for use	- temporary relief of minor muscle and joint aches, pains and stiffness - temporary relief of muscle spasm - temporary relief of minor pain and stiffness associated with arthritis	- temporary relief of minor muscle and joint pain - temporary relief of muscle spasm - temporary relief of minor pain and stiffness associated with arthritis - promoting relaxation of the	- temporary increase in local blood circulation - temporary relief of minor muscle and joint aches, pains and stiffness - relaxation of muscles - temporary relief of muscle spasm

		- promoting relaxation of the muscle tissue - temporary increase in local blood circulation	muscle tissue - temporary increase local blood circulation	- temporary relief of minor pain and stiffness associated with arthritis
15.	touch screen interface	+	+	-
16.	color LCD screen	+	+	-
17.	external memory	+	+	-
18.	functional cart option	+	+	+
19.	number of output channels	1	1	1
20.	modifiable waveform parameters / customize treatment parameters	+	+	+
21.	possibility to switch the laser on and off	+	+	+
22.	interlock	+	+	+
23.	emergency off switch	+	+	+
24.	laser warning signal	+	+	+
25.	spacer	+ (optional)	+	-
26.	number of output modes	2	3	2
27.	output modes	continuous wave, serial pulse,	continuous wave, serial pulse, intense super pulse	continuous wave, serial pulse
28.	favorites / named user defined programs	+	+	+
29.	laser performance testing	+	N/A	+
30.	electronic key lock	+	N/A	+
31.	calculated and displayed energy	+	+	+
32.	displayed treatment time	+	+	+
33.	wavelength aiming beam [nm]	650	635 or 650	670
34.	wavelength laser beam [nm]	810 and 980	800 and / or 970	820 or 850
35.	output power [W]	1 - 7	0.1 - 12	0.1 - 1.44
36.	repetition rate f [Hz]	1 – 50 CW	1 – 20 000 CW Intense Super Pulse (ISP)	8 – 10 000 CW
37.	area output spot size [cm ²]	0.8	1 - 5	0.07 – 31.2
38.	duty cycle [%]	10 - 50	50	90

f.) Summary Comparison with predicate devices

The *OptonPro* shares the same intended use and the same or similar basic characteristics and features as the predicate devices. In addition, any differences in their technological characteristics are explained to demonstrate in this submission that these differences do not raise any new questions of safety and effectiveness.

g.) Non-clinical Tests Performed

Validation documentation, product testing and a comparison of the technical characteristics and features according to relevant standards were provided to demonstrate that *OptonPro* is as safe and effective in its intended use.

The *OptonPro* achieves a therapeutic temperature range of 40 – 45°C as accepted by the FDA.

The maximal transition time for reaching this therapeutic temperature range is 5 min.

The therapeutic temperature range was maintained for a recommended treatment time of 10 min.

The temperature measurements were conducted on a few test candidates on different physical locations.

h.) Conclusion Substantial Equivalence

Drawn from the comparison between the predicate devices and the *OptonPro* devices it demonstrates that the *OptonPro* device is as safe and effective as the predicate devices and therefore are substantially equivalent to the compared devices on the basis of similarities in operating principles, intended use and functional performance.