August 4, 2021

SLK Medical GmbH
Matthew Reid
Product Manager
SLK Medical GmbH
298-24, Gongdan-Ro
Gunpo-Si, Gyeonggido 15809
South Korea

Re: K210913
Trade/Device Name: V12 PRO
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: May 25, 2021
Received: June 1, 2021

Dear Matthew Reid:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210913

Device Name
V12 PRO

Indications for Use *(Describe)*
The V12 PRO is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The V12 PRO simulates kneading and stroking of tissues by using an inflatable garment.

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
K210913

1. SUBMITTER

SLK Medical GmbH
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44147 Dortmund, Germany

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Official Contact: Matthew Reid – Product Manager Tel: +49 163 7550203

2. DEVICE

Name of Device: V12 PRO

Classification Code: CFR Classification section 890.5650

Product code: IRP

Class: 2

3. PREDICATE DEVICE

The V12 PRO is substantially equivalent to the following predicate device:

- *Ballancer 505 System, Model 1201 - AC (K150269)*

4. DEVICE DESCRIPTION

V12 PRO utilizes a software-controlled air compression pump, which sequentially inflates and deflates cells within a compression garment (sleeve) that is put around a limb. V12 PRO consists of an air pump, air pressure sensor, and sleeves working together as one unit. The air pump is connected to the dedicated sleeves via a series of hoses; each sleeve has twelve (12) compression chambers. The compression massage direction is from limb end to body center. By inflating the air chambers sequentially and then deflating as one cycle, the pressure can be adjusted to avoid any discomfort to the patient. The sleeve works under the action of sensor and microprocessor. Software controls the timing and pressure reflected by the sensor, cycling airflow into and out of the sleeves to compress body.

The V12 PRO consist of an air compressor unit with a control system, an inflatable garment (arms, legs, trouser and jacket), silicon air tubing with proprietary connectors for connecting the device to the appliance, and a power cord.

The user interface on the V12 PRO is a Membrane Keypad with dome switches. The settings are shown on a 3.2" LCD Screen.

5. INDICATIONS FOR USE

The V12 PRO is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The V12 PRO simulates kneading and stroking of tissues by using an inflatable garment.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Intermittent pneumatic compression is the technological principle for both the subject and the predicate device. The subject and the predicate devices are based on the following same technological elements:

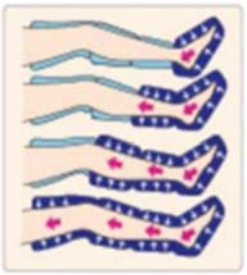
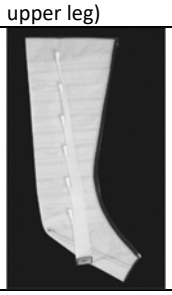
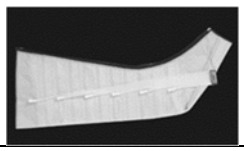
- Electronically controlled Air Pump with inflatable compression garments (arm, leg, jacket and Hip garment), which conducts a sequential compression of the patient's limbs.

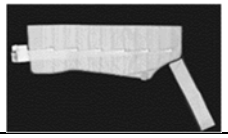
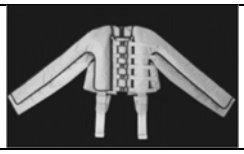
The following technological differences exist between the subject and the predicate devices:

- While V12 PRO uses a turning dial to set the pressure, the predicate uses push buttons for this function.

TABLE FORMAT

Device	Subject Device	Predicate	Comparison
Manufacturer	SLK Medical GmbH	Ballancer 505 System	-
510(k) Number	K210913	K150269	-
Model Name	V12 PRO	Model 1201-AC	-
Classification	Class II Device, IRP (21 CFR 890.5650)	Class II Device, IRP (21 CFR 890.5650)	Same
Indications for Use	V12 PRO is a Compression Therapy System is intended for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas in people who are in good health. The V12 PRO Therapy System simulates kneading and stroking of tissues by using an inflatable garment.	Ballancer 505 is a pneumatic massage system intended to provide gradient pressure in areas, which the inflatable garment is applied. The Ballancer 505 System is indicated for: * Simulating kneading and stroking of the tissues by use of an inflatable garment * Temporary increase circulation in areas which the garment is applied * Temporary relief of minor muscle aches and pains	Similar
OTC or Rx	OTC	OTC	Same
Environment of Use	Clinics, hospital, athlete training, and home environments	Not publicly available	-
Standards	- IEC ISO 13485 - IEC ISO 14971 - IEC ISO 10993 - IEC 60601-1 - IEC 60601-1-11 - IEC 60601-1-2 - IEC 60601-1-6	Not publicly available	Meets consensus standards for ES, EMC, Biocompatibility
Mode of Compression	Sequential Gradient	Not publicly available	-
Power Source	110 -230 V 50/60 Hz	Not publicly available	-
Therapy Time	User determines therapy time. Choose from 15 to 60 minutes session time.	Not publicly available	-
Max Pressure **Min Pressure**	15-80 mmHg	Not publicly available	-
Number of Chambers	12 Chambers	Not publicly available	-
Compression Garment Sleeve Material	Nylon with a Polyurethane laminate	Not publicly available	-
Housing Materials	Molded ABS enclosure	Not publicly available	-

And Constructions			
Patient contact	Non-conductive attachments	Not publicly available	-
Power Consumption	20W	Not publicly available	-
Cycle time	1 min 15 sec	Not publicly available	-
Photo and Size	 6.69" x 7.87" x 7.87”	Not publicly available	-
Weight	4.4 pounds	Not publicly available	-
Modes (inflation sequences, all preprogrammed)	Inflates chambers from bottom up but maintains pressure in lower chambers as works its way to top. Then all chambers release pressure at same time once all chambers have sequentially inflated.	Not publicly available	-
Modes (visual description)	Sequential 	Not publicly available	-
“Leg” Attachment	Leg (consisting of foot, calf, knee, upper leg)	Not publicly available	-
Leg Attachment Photos		Not publicly available	-
Attachment Sizes	32” x 30” 	Not publicly available	-
“Pant” Attachment	Pant (consists of foot, calf, knee, upper leg, glutes, hips, lower back)	Not publicly available	-

Pant Attachment Photo		Not publicly available	-
“Arm” Attachment	Arm (consisting of entire arm, shoulder, upper chest and back)	Not publicly available	-
Arm Attachment Photos		Not publicly available	-
Arm Attachment Sizes	22” x 29” 	Not publicly available	-
“Jacket“ Attacments	Jacket (consisting of entire arms, shoulder, upper chest and back)	Not publicly available	-
Jacket Attachment Photos		Not publicly available	-
SW/Firmware/ Microprocessor control	Firmware / Microprocessor	Not publicly available	-
Technology	Compressor and valve system which sequentially inflates cells sequentially	Not publicly available	-

7. PERFORMANCE DATA

All tests were performed with the reference device VariLymph 12 Pro (V12 PRO).

There are no performance standards under the Federal Food, Drug and Cosmetic Act, for a compressible limb sleeve device. The testing included various performance tests and software validation tests, designed to ensure that the device met all its functional specifications. Tests have been performed to ensure the device complies with industry and safety standards.

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility testing

The biocompatibility evaluation for the V12 PRO device was conducted in accordance with the FDA "Use of International Standards ISO-10993, #Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Irritation
- Sensitization

The intended use of the product involves contact with the intact skin for a period of less than 24 hours. To evaluate the biocompatibility of the product, a cytotoxicity test as per ISO 10993-5:2009 and skin irritation and sensitization test as per ISO 10993-10:2013 were therefore considered sufficient. Any knowledge to be gained from further biocompatibility testing with this product would not justify the unnecessarily high level of harm to experimental animals involved. As per ISO 10993-1:2009 such tests were not performed. The type and scope of the tests performed complies with the specifications as per ISO 10993-1:2009.

Electrical Safety and Electrical Compatibility (EMC)

Electrical safety and EMC testing were conducted on the V12 PRO. The system complies with the IEC 60601-1. A justification how all the applicable statutory or regulatory criteria of the EN 60601-1 are met through recognition of IEC 60601-1 was provided.

IEC 60601-1-2:2014 standard for EMC and IEC 60601-1-11 Medical electrical equipment: General requirements for basic safety and essential performance was tested as well.

Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA´s Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices."

Pressure Distribution Comparison Test

The purpose of the test was to find out if the V12 PRO has a pressure distribution comparable to that of the predicate (Ballancer 505 System) to ensure that the device is as safe and effective as a legally market device.

Summary: Based on the tests it can be concluded that there are a few differences between the pressure curves but both products show a similar compression pressure cure in longitudinal direction. From this result it can be also concluded that both devices have the same technological characteristics. The V12 PRO was found to have a safety and effectiveness profile that is similar to the predicate device.

8. CONCLUSION

The conclusion drawn from the above Performance Testing and comparison to predicate device is that the V12 PRO is substantially equivalent in safety and efficacy to the predicate device listed above.

The non-clinical data support the safety of the device and the hardware and software verification und validation demonstrate that the V12 PRO should perform as intended in the specified use conditions. The data demonstrates that the V12 PRO device performs comparably to the predicate device that is currently marketed for the same intended use (temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health). V12 PRO device uses sequential inflation and deflation of cells within compression sleeves put around a limb. Inflation/Deflation, pressures, pressure distribution and sequences are similar to those of the predicate device.