August 19, 2020

SLK Medical GmbH
Matthew Reid
Product Manager
Oberste-Wilms-Str. 15a
Dortmund, 44309 De

Re: K193476
Trade/Device Name: SLK VariLymph 12 Pro
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: November 25, 2019
Received: December 16, 2019

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 Fernando Aguel
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193476

Device Name
SLK VariLymph 12 Pro (SLK V12 Pro)

Indications for Use *(Describe)*
Primary lymphedema (for example, congenital lymphedema/ milroy's disease)
Secondary lymphedema (for example, post-mastectomy, chronic edema, post-traumatic edema)
Venous disorders (for example, venous insufficiency, varicose veins, venous stasis ulcers)
Dysfunction of the muscle pump (for example, promotion of wound recovery, reduction of edema and lower limb pain following trauma and sports injuries)

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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March, 05th 2020

510(k) Summary

I. SUBMITTER

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Official Contact: Matthew Reid – Product Manager

Tel: +49 163 7550203

II. DEVICE

Name of Device: SLK VariLymph 12 Pro

Common / Usual Name: SLK V12 Pro

Classification Code: CFR Classification section 870.5800 Compression limb sleeve

Product code: JOW

Classification: Class II medical Device

III. PREDICATE DEVICE

The SLK VaryLymph 12 Pro Compression Therapy Device is substantially equivalent to the following predicate device:

LYMPHA PRESS OPTIMAL MODEL 1201AP COMPRESSIBLE LIMB SLEEVE DEVICE, K082149

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IV. DEVICE DESCRIPTION

SLK VariLymph 12 Pro Compression Therapy Device utilizes a software-controlled air compression pump, which sequentially inflates and deflates cells within a compression garment (sleeve) that is put around a limb. This helps to push excessive interstitial fluid in the treated limb, back into the venous and lymphatic systems; improve limb circulation; and thus, treat the symptoms of a variety of lymphatic disorders, venous disorders and dysfunction of the "muscle pump". The device consists of a main console and compression garments. The main control contains an air compressor that is regulated by an electro-mechanical mechanism, including pressure sensors and a rotating dis controlling air outflow. The regulated compressed air is transferred via an air distributor through a series of hoses to a sleeve garment. Each garment contains 12 pressure cells. The sleeve fits on the affected limb and can easily adjusted to any limb size within the sleeve tolerance. The devices are powered from a system supply voltage (230V / 110V).

The SLK VariLymph 12 Pro (SLK 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 SLK VariLymph 12 Pro is a Membrane Keypad with dome switches. The settings are shown on a 3,2" LCD Screen.

The device is intended to be used by the patient at home, as well as by physicians at clinics or hospitals.

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V. INDICATIONS FOR USE AND CONTRAINDICATIONS

The SLK VariLymph 12 Pro is intended for the following indications for use:

- Primary lymphedema (for example, congenital lymphedema/ milroy's disease)
- Secondary lymphedema (for example, post-mastectomy, chronic edema, post-traumatic edema)
- Venous disorders (for example, venous insufficiency, varicose veins, venous stasis ulcers)
- Dysfunction of the muscle pump (for example, promotion of wound recovery, reduction of edema and lower limb pain following trauma and sports injuries)

The device is intended to be used by the patient (adults=8 or older) at home, as well as by physicians at clinics or hospitals.

The SLK VariLymph 12 Pro should not be used in the following cases:

- Recent myocardial infarct
- Cardiac and renal caused edema
- Acute erysipelas
- Acute soft-part-trauma of extremities
- Occlusive processes in the lymphatic drainage area
- Extensive thrombophlebitis, thrombosis or suspected thrombosis
- Pulmonary edema
- Decompensated cardiac insufficiency
- Severe unestablished hypertension
- neuropathy

These indications and contraindications are identical to the predicate.

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VI. 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 trouser garment), which conducts a sequential compression of the patient's limbs

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

- While Varilymph 12 Pro uses a turning dial to set the pressure, the predicate uses push buttons for this function

VII. PERFORMANCE DATA

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 SLK VariLymph 12 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

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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 an epicutan 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 SLK VariLymph 12Pro. 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 60601-2:2014 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." The software of this device was considered "minor" level of concern, since all answers to the questions in Table 1 and 2 in the Guidance are no.

Usability

Usability Test Protocol IEC 60601-1-6 / IEC 62366

Mechanical and acoustic testing

Shock test according to IEC 60601-1-11 and IEC 60068-2-27
Vibration test according to IEC 60601-1-11and IEC 60068-2-64

**all test reports provided by SLK Prüf- und Zertifizierungs GmbH follow the IECEE CB scheme - IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components*

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Animal Study

Any knowledge to be gained from testing with this product would not justify the unnecessarily high level of harm to experimental animals involved.

Pressure distribution Comparison Test

The purpose of the test was to find out if the SLK VariLymph 12 Pro has a pressure distribution comparable to that of the predicate (Lympha Press Optimal of Mego Afek) to ensure that the device is as safe and effective as a legally market device.

Summary: Based on the Expert Report by Berlin Cert GmbH 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 SLK VariLymph 12 Pro was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSION

Since the predicate device was cleared based in part on the results of clinical studies, performance data was required to support substantial equivalence. The conclusion drawn from the above Performance Testing and comparison to predicate device is that the SLK VariLymph 12 Pro compression therapy device 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 SLK VariLymph 12 Pro device should perform as intended in the specified use conditions. The clinical data demonstrate that the SLK VariLymph 12 Pro device performs comparably to the predicate device that is currently marketed for the same intended use (treatment of venous and lymphatic disorders and dysfunction of the muscle pump). The 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.

Sincerely,

Martin Herberg
Chief Executive Manager

SLK Medical GmbH