September 21, 2021

Koya Medical, Inc.
% Alex Chang
Regulatory Affairs Consultant
BioDesign Regulatory Services, LLC
16185 Los Gatos Blvd.
Los Gatos, California 95032

Re: K212287
Trade/Device Name: Dayspring Lite
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: August 23, 2021
Received: August 24, 2021

Dear Alex Chang:

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,

Nicole Gillette
Assistant Director (Acting)
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212287

Device Name
Dayspring Lite

Indications for Use *(Describe)*

Dayspring Lite is a prescription only wearable compression system that is intended for use in a clinic or home setting by medical professionals and patients who are under medical supervision, for the treatment of the following conditions:

- Chronic edema
- Lymphedema
- Venous insufficiency
- Wound healing

Dayspring Lite is developed on a wearable compression technology platform, which is designed to provide mobility for patients.

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.

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

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1. 510(K) SUMMARY

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

I. SUBMITTER: Koya Medical, Inc.
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DATE PREPARED: Aug 20, 2021

II. DEVICE:

TRADE NAME: DAYSPRING LITE

CLASSIFICATION NAME: COMPRESSIBLE LIMB SLEEVE (21 CFR 870.5800)

DEVICE CLASSIFICATION: CLASS II

PRODUCT CODE: JOW

III. PREDICATE DEVICES: K143185, K210885

IV. DEVICE DESCRIPTION:

Dayspring Lite consists of two main components: a controller and garment. The garment is powered by an active smart compression technology that is instant-acting, and silent. This technology uses a Nickel Titanium (Ni-Ti) shape-memory alloy that is activated by the controller. A liner is worn as an accessory under the device to prevent direct patient contact with the garment. The garment is wrapped around the patient's affected area so that the device fits snugly. The device has up to 14 independently controlled sections in each limb. The controller is pre-programmed to provide sequential compression therapy to the affected area. The device is powered by a rechargeable Lithium-ion battery pack. The device was developed to provide patients with untethered access and a functional range of motion and mobility.

V: INDICATION FOR USE:

Dayspring Lite is a prescription only wearable compression system that is intended for use in a clinic or home setting by medical professionals and patients who are under medical supervision, for the treatment of the following conditions:

- Chronic edema
- Lymphedema
- Venous insufficiency
- Wound healing

Dayspring Lite is developed on a wearable compression technology platform, which is designed to provide mobility for patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE

DEVICE:

Feature	**Subject Device**	**Primary Predicate Device (K210885)**	**Additional Predicate Device (K143185)**
Electrical Requirements	Rechargeable Li-ion Battery Pack, AC Charging Adapter	Rechargeable Li-ion Battery Pack, AC Charging Adapter	100-240 VAC 50/60 Hz to AC Adapter with output voltage of 12.0V DC and 3.0A
Output	Sequential gradient Pressure	Sequential calibrated gradient Pressure	Sequential gradient Pressure
Mechanism of Action	Exertion of sequential pressure to affected area	Exertion of sequential pressure to affected area	Exertion of sequential pressure to affected area
Principles of Operation	Lithium-ion battery powered integrated shape memory alloy channels creating compressive pressure	Lithium-ion battery powered integrated shape memory alloy channels creating compressive pressure	Electrically powered integrated pneumatic air channels creating compressive pressure
Controller Enclosure Material	All plastic construction	All plastic construction	All plastic construction
User Interface	Pushbuttons. Also available is Bluetooth Low Energy (BLE)	Pushbuttons. Also available is Bluetooth Low Energy (BLE)	Pushbuttons Mobile application or BLE not available

	Module for communication with mobile application on mobile device	Module for communication with mobile application on mobile device	
Software/Hardware	Analog and digital electronic with microprocessor	Analog and digital electronic with microprocessor	Analog and digital electronic with microprocessor
Garment Material	Nylon fabric with velcro straps	Nylon fabric with velcro straps	Nylon fabric with velcro straps
Stockinette/Liner	Class I biocompatible liner provided with the unit	Class I biocompatible liner provided with the unit	Class I biocompatible liner provided with the unit

VII: PERFORMANCE DATA:

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

Biocompatibility Testing
The subject device is considered a surface contacting device with prolonged exposure duration considering potential cumulative use. The surface contacting material described was previously evaluated for biocompatibility per ISO 10993-1, ISO 10993-5, and ISO 10993-10.

Sterilization

The subject device is non-sterile, and components are unlikely to deteriorate with age. Accelerated 1 year accelerated shelf-life testing was performed and shown to support shelf stability.

Electrical Safety and Electromagnetic Compatibility (EMC)
The subject device was evaluated based on the following applicable performance and safety standards: IEC 60601-1:2012, IEC 60601-1-11:2015 and IEC 60601-1-2:2014. Results demonstrated that the subject device was compliant to all applicable performance and safety standards.

Software Verification and Validation Testing
The subject device includes embedded firmware in the controller which has the ability to connect with custom software installed on a mobile device. The system software exhibits a moderate level of concern.

Software lifecycle planning and documentation as well verification and validation testing were performed in accordance with IEC 62304:2015 and as recommended by the following FDA Guidance documents for Industry and FDA Staff:

- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices
- Guidance for Industry and Food and Drug Administration Staff Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
- Guidance for Industry, FDA Reviewers and Compliance on Post market Management of Cybersecurity in Medical Devices

In accordance with IEC 62304:2015 and FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, the following software lifecycle documentation has been developed. Testing demonstrated that the subject device met all software requirements.

Document	**Status**
Software Development Plan	Completed
Software Requirements Specifications (SRS)	Completed
Software Design Specification (SDS)	Completed
Off-the-Shelf Software Management	Completed
Software Configuration Management	Completed
Software Architecture	Completed
Cybersecurity Analysis	Completed
Software Coding Standard	Completed
Traceability Analysis	Completed
Software Verification and Validation	Completed / Pass

Summary of Performance Testing

The subject device was evaluated based on the following benchtop performance tests.

Performance Study	Overview	Status
Storage and Shelf-Life Stability	1 Year aging guided by Q10 Theory & ASTM F1980	Completed / Pass
Transportation Simulation	ASTM D4169	Completed / Pass
Pressure Verification Testing	Pressure capable of delivering 0-100 mmHg compression pressures.	Completed / Pass

Packaging, Shelf Life and Transport Stability Testing

The subject device was packaged in a corrugated shipper. The packaging configuration was evaluated based on ASTM D4169. Prior to running the transit simulation, the test sample underwent 1 year accelerated aging based on ASTM F1980 - Standard Guide for Accelerated Aging of Medical Device Packages and was subjected to environmental conditioning to confirm shelf-life stability. Post-simulation, functional testing of the subject device was performed and showed that it continued to meet all functional specifications.

Benchtop Pressure Testing

Benchtop pressure testing was performed to verify the pressure range applied by the subject device was equivalent to pressure applied by the K143185 and K210885 predicate systems.

Test Summary

The subject device has been investigated and tested against and complies with the following voluntary standards:

Standards	Standards Organization	Standards Title
60601-1:2005 + CORR: 1:2006 + CORR. 2:2007 + A1:2012 (Edition 3.1)	IEC	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
60601-1-11:2015	IEN	Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

60601-1-2:2014 (Edition 4.0)	IEC	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
62304:2015 (Edition 1.1)	IEC	Medical devices software –software life cycle processes
10993-1:2018	ISO	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
10993-5: 2009	ISO	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
10993-10: 2010	ISO	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
D4169-16	ASTM	Standard Practice for Performance Testing of Shipping Containers and Systems
14971:2013	ISO	Medical devices – Application of risk management to medical devices

Testing has been performed and all components, subassemblies and/or full devices and systems have met the required specifications for the completed tests.

Animal Study
Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Clinical Study
Clinical testing was not required to demonstrate the safety and effectiveness of the Koya Dayspring Lite. Instead, substantial equivalence is based upon benchtop performance testing.

VIII. CONCLUSION:

The data included in this submission demonstrates that Dayspring Lite is substantially equivalent to the cleared and marketed primary predicate for its intended use.