April 23, 2021

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

Re: K210885
Trade/Device Name: Dayspring
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: March 22, 2021
Received: March 25, 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,

Claire L. Hambright -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K210885

Device Name
Koya Dayspring

Indications for Use *(Describe)*
The Koya Dayspring system 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 to increase lymphatic flow in the treatment of many conditions such as:

- Lymphedema
- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sports injuries
- Post immobilization edema
- Venous insufficiency
- Reducing wound healing time
- Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, or arterial and diabetic leg ulcers
- Lipedema
- Phlebolymphedema

The Dayspring system 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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"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."

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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Establishment Registration: 3017424826

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Regulatory Consultant
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DATE PREPARED: April 21, 2021

II. DEVICE:

TRADE NAME: DAYSPRING

CLASSIFICATION NAME: COMPRESSIBLE LIMB SLEEVE

DEVICE CLASSIFICATION: CLASS II

PRODUCT CODE: JOW

III. PREDICATE DEVICES:

Primary Predicate
Manufacturer: Koya Medical, Inc.
Trade Name: Koya Dayspring
510(k): K193288

Additional Predicate
Manufacturer: Tactile Systems Technology, Inc.
Trade Name: Flexitouch Plus System (PD32-G3)
510(k): K203178

IV. DEVICE DESCRIPTION:

The Dayspring system consists of two main components: a controller and garment. The garment is powered by an active smart compression technology that is calibrated, instant-acting, and silent. This technology uses a Nickel Titanium (Ni-Ti) shape-memory alloy programmed 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 can be programmed to provide sequential compression therapy to the affected area over a range of 0-100 mmHg. 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: INDICATIONS FOR USE:

The Dayspring system 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 to increase lymphatic flow in the treatment of many conditions such as:

- Lymphedema
- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sports injuries
- Post immobilization edema
- Venous insufficiency
- Reducing wound healing time
- Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, or arterial and diabetic leg ulcers
- Lipedema
- Phlebolymphedema

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

<u>Differences in the indications from the cleared primary predicate device (K193288):</u>
With the addition of the lower extremity garments, the Dayspring System, which provides a range of 0 – 100 mmHg of active compression, can now allow for the treatment of the following new indications (conditions):

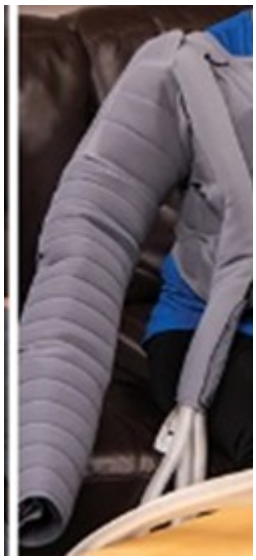
- Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, or arterial and diabetic leg ulcers
- Lipedema
- Phlebolymphedema

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:

Feature	**Subject Device**	**Primary Predicate Device** (K193288)	**Additional Predicate Device (**K203178)
Indications for use	The Koya Dayspring system 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 to increase lymphatic flow in the treatment of many conditions such as: ● Lymphedema	The Koya Dayspring system 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: ● Lymphedema ● Primary lymphedema	The Flexitouch Plus System and garments for legs, arms, trunk, and chest are intended for use by medical professionals and patients who are under medical supervision to increase lymphatic flow in the treatment of many conditions such as: ● Lymphedema ● Primary lymphedema ● Post mastectomy

	● Primary lymphedema ● Post mastectomy edema ● Edema following trauma and sports injuries ● Post immobilization edema ● Venous insufficiency ● Reducing wound healing time ● Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, or arterial and diabetic leg ulcers ● Lipedema ● Phlebolymphedema The Dayspring system is developed on a wearable compression technology platform, which is designed to provide mobility for patients.	● Post mastectomy edema ● Edema following trauma and sports injuries ● Post immobilization edema ● Venous insufficiency ● Reducing wound healing time The Koya Dayspring system is developed on a wearable compression technology platform, which is designed to provide mobility for patients.	edema ● Edema following trauma and sports issues ● Post immobilization edema ● Venous insufficiency ● Reducing wound healing time ● Treatment and assistance in healing stasis dermatitis, venous stasis ulcers, arterial ulcers, and diabetic leg ulcers ● Lipedema ● Phlebolymphedema The Flexitouch Plus System and garments for the head and neck are intended for use by medical professionals and patients who are under supervision for the treatment of head and neck lymphedema.
Electrical Requirements	Rechargeable Li-ion Battery Pack, with 0.800 A input from 90-264 VAC 50/60 Hz to AC Adapter, with output voltage of 25.0V DC and 3.0A	Rechargeable Li-ion Battery Pack, with 1.7A input from 100-240 VAC 50/60 Hz to AC Adapter, with output voltage of 19.0V DC and 3.4A	100-240 VAC 50/60 Hz to AC Adapter with output voltage of 12.0V DC and 3.0A
Output	Sequential calibrated gradient Pressure	Sequential calibrated gradient Pressure	Sequential calibrated 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
Device Total Pressure Range	0-100 mmHg	0-100 mmHg	0-100 mmHg
Controller Unit			
Controller unit size and weight	3.4" x 5.2" x 1.5" 0.80 lbs	3.2" x 3.6" x 1.79" 0.73 lbs	8"x10"x8" 6.2 lbs
Controller Enclosure Material	All plastic construction	All plastic construction	All plastic construction
User Interface	Pushbuttons. Also available is Bluetooth Low Energy (BLE) Module for communication with mobile application on mobile device	Pushbuttons. Also available is Bluetooth Low Energy (BLE) Module for communication with mobile application on mobile device	Pushbuttons Mobile application or BLE not available
Software/Hardware	Analog and digital electronic with microprocessor	Analog and digital electronic with microprocessor	Analog and digital electronic with microprocessor

Garment			
Garment Material	Nylon fabric with velcro straps	Nylon fabric with velcro straps	Nylon fabric with velcro straps
Stockinette/Liner	Class I biocompatibile liner provided with the unit	Class I biocompatibile liner provided with the unit	Class I biocompatibile 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 patient-contacting material consists of a circular knit liner made of a hydrophilic nylon fiber and is commonly used for compression liner applications. The surface contacting material described has been evaluated for biocompatibility per ISO 10993-1, ISO 10993-5, and ISO 10993-10. Results demonstrated that the subject device was compliant to all applicable biocompatibility safety standards.

Sterilization & Shelf-life Testing

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 Postmarket Management of Cybersecurity in Medical Devices

Mechanical Testing

The subject device was also evaluated based on the following additional benchtop performance

tests.

Performance Study	Overview	Status
Transportation Simulation	ASTM D4169	Completed / Pass
Pressure Verification Testing	Pressure capable of delivering 0-100 mmHg compression pressures.	Completed / Pass

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 system. Instead, substantial equivalence is based upon benchtop performance testing.

VIII. CONCLUSION:

The data included in this submission demonstrate that the modified Koya Dayspring™ is substantially equivalent to the cleared primary predicate device, the Koya Dayspring™ (K193288).