June 16, 2020

Koya, Inc.
% Robert Packard
President
Medical Device Academy, Inc.
345 Lincoln Hill Road
Shrewsbury, Vermont 05738

Re: K193288
Trade/Device Name: Koya Dayspring
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: May 19, 2020
Received: May 19, 2020

Dear Robert Packard:

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)*
K193288

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 for the treatment of the following:

- Lymphedema
- Primary lymphedema
- 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.

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.

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
PRAStaff@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."

K193288 – 510(k) SUMMARY

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

I. SUBMITTER

Koya, Inc.
357 Tehama St., Suite 1
San Francisco, CA, 94103 USA
+1.415.851.0337
Fax: N/A
Contact Person: Andy Doraiswamy, PhD
Date Prepared: February 21, 2020

II. DEVICE

Name of Device:	Koya Dayspring™
Classification Name:	Compressible Limb Sleeve
Regulation:	21 CFR § 870.5800
Regulatory Class:	Class II
Product Classification Code:	JOW

III. PREDICATE DEVICE

Predicate Manufacturer:	Tactile Systems Technology, Inc. (dba Tactile Medical)
Predicate Trade Name:	Flexitouch Plus System, Model PD32-G3
Predicate 510(k):	K170216
Reference Device:	K162481

IV. DEVICE DESCRIPTION

The Koya Dayspring™ system 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 a controller system. A disposable stockinette is worn as an accessory under the device to prevent direct patient contact with the device. The device is wrapped around the patient's arm so that the device fits snugly. The device has up to 16 independently controlled sections in each arm. 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 while treating chronic lymphedema.

V. 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 for the treatment of the following:

- Lymphedema
- Primary lymphedema
- Post mastectomy edema
- Edema following trauma and sports injuries

- Post immobilization edema
- Venous insufficiency
- Reducing wound healing time

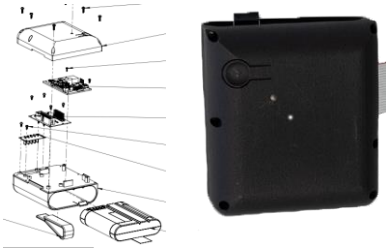
The system is developed on a wearable compression technology platform, which is designed to provide mobility for patients.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

A reference device, K162481, was provided to address the concern that the subject device is using a different principle of operation (i.e., shape-memory materials) when compared to the predicate device (i.e., air pressure). The reference device identified uses the same principle as the subject device.

The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

Feature	Subject Device (K193288)	Predicate Device (K170216)
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 for the treatment of the following: • Lymphedema • Primary lymphedema • 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.	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, for 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 The Flexitouch Plus System and garments for the head and neck are intended for use by medical professionals and patients who are under medical supervision for the treatment of head and

		neck lymphedema.
Electrical Requirements	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
Mechanism of Action	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	Electrically powered integrated pneumatic air channels creating compressive pressure
Device Total Pressure Range	0-100 mmHg	0-100 mmHg
Controller Unit		
Controller unit size and weight	3.3” x 3.6” x 0.8” 3 lbs	8”x10”x8” 6.2 lbs
Controller Enclosure Material	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 Mobile application or BLE not available
Mechanism of Action	Exertion of sequential pressure to affected area	Exertion of sequential pressure to affected area
Software/Hardware	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
Stockinette	Class I biocompatibile liner provided with the unit	Class I biocompatibile liner provided with the unit
Chambers/Sections	Up to 16 chambers for the extremity Short: 12 Medium: 14 Long: 16	Up to 16 chambers for the extremity Short: 12 Medium: 14 Long: 16

VII. PERFORMANCE DATA

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

Sterilization & Shelf-life Testing

Device is non-sterile, and components are unlikely to deteriorate with age with the exception of Li-ion battery. Battery shelf-life and charge/discharge testing data was provided.

Biocompatibility Testing

The patient contacting portion of the device is the stockinette liner which is a biocompatible, Class 1 device that is marketed in the USA. Since the material comes in contact with intact skin with an exposure duration of less than 24 hours, it was tested to ensure the safety using cytotoxicity study (ISO 10993-5), sensitization study (ISO 10993-10), and irritation study (ISO 10993-10). All results were found to be acceptable and the material found to safe for the intended use.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing included:

- ANSI AAMI ES60601-1:2005/(R)2012 And A1:2012,
- IEC 60601-1-2 Ed. 4.0
- IEC 60601-1-11 Ed. 2.0
- IEC 62133-2 Ed. 1.0

Software Verification and Validation Testing
Software verification and validation testing was performed in accordance with IEC 62304 Ed. 1.1. Additional software verification and validation testing was conducted and documentation was provided 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 and acoustic Testing
A benchtop mechanical testing study was performed to compare the pressure applied by the subject device with the pressure applied by the predicate device. Additionally, transport shipping testing was conducted in accordance with ASTM D4169.

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

Clinical Studies
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. CONCLUSIONS

The data included in this submission demonstrates that the Koya Dayspring™ is substantially equivalent to the legally marketed predicate device, Flexitouch Plus® PD32-G3 (K170216).