September 19, 2019

Menlo Brands LLC
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive Suite 510k
Saint Paul, Minnesota 55114

Re: K192252
Trade/Device Name: ProPerformance Recovery System
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered inflatable tube massager
Regulatory Class: Class II
Product Code: IRP
Dated: August 19, 2019
Received: August 20, 2019

Dear Prithul Bom:

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 Vivek Pinto, Ph.D.
Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192252

Device Name
ProPerformance Recovery System

Indications for Use *(Describe)*
The Speed Hound ProPerformance Recovery System 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 Speed Hound Recovery System 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

Date Prepared:	15 Aug 2019
Applicant	Menlo Brands LLC 2045 Avy Avenue Menlo Park, CA 94025 Tel – 650 796 8905
Official Contact:	Sam Chi, CEO
Proprietary or Trade Name:	ProPerformance Recovery System
Common/Usual Name:	Powered Inflatable Tube Massager
Classification Name:	IRP - Massager Powered Inflatable Tube (CFR 890.5650)
Predicate Devices:	K182668 – Rapid Reboot Compression Therapy System

Device Description:
This submission is for the Speed Hound ProPerformance Recovery System. The Speed Hound ProPerformance Recovery System is a powered inflatable tube massager. It is intended to temporarily relieve minor muscle aches and pains, and to temporarily increase circulation to the treated areas. It simulates manual kneading and stroking of tissues by use of an inflatable pressure cuff. The device is to be used by people who are in good health.

The device is a Class II, type BF applied part that receives power through a non-detachable power cord

The ProPerformance Recovery System consists of an air compressor unit with a control system, an inflatable "garment" (arms, legs and hips), plastic air tubing with a proprietary connector for connecting the device to the garment A description of each of these components is provided below.

The hardware and software of this device is identical to the model PT1003 by Xiamen Senyang Co., Ltd., cleared under 510(k) K181409

The"garments" (leg, arm and hip) and the plastic air tubing are of identical materials to the components of the FDA-cleared PT1003 (K181409).

510(k) Summary

Indications for Use:

The Speed Hound ProPerformance Recovery System 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 Speed Hound Recovery System simulates kneading and stroking of tissues by using an inflatable garment.

Patient Population:

Adults

Environments of Use:

Clinics, hospital, athlete training, and home environments

510(k) Summary

Table 5.1 - Table of the Similarities and Differences of Predicate vs. Proposed Device

Model Name **510(k) Number**	**New Device** **ProPerformance Recovery System** **510(k) TBD**	**Predicate Device** **Rapid Reboot** **510(K) K182668**	**Comment**
Classification	Class II Device, IRP (21 CFR890.5650)	Class II Device, IRP (21 CFR890.5650)	Identical
Indications for use	The Speed Hound ProPerformance Recovery System 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 Speed Hound Recovery System simulates kneading and stroking of tissues by using an inflatable garment	The Rapid Reboot 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 ingood health. The Rapid Reboot Compression Therapy System simulates kneading and stroking of tissues by using an inflatable garment.	Identical
OTC or Prescription	OTC	OTC	Identical
Environment of Use	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	Identical
Compliance with Voluntary standards	ES 60601-1, IEC 60601-1-2, IEC 60601-1-11	IEC 60601-1, IEC 60601-1-2	ProPerformance Recover System meets home use standard
Mode of Operation	Sequential/Peristaltic	Sequential/Peristaltic	Identical
Power	110-125Vac 60Hz	110 V, 60Hz	Equivalent
Device **Pressure range**	20-200 mmHg	20 - 200 mmHg	Identical
Treatment Time	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time.	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time.	Identical
Garments contact surface	Nylon with a Polyurethane	Nylon with a Polyurethane	Identical to **reference**

510(k) Summary

material	laminate	laminate	**device** as below
Leg Attachment	Yes	Yes	Identical in size and construction
Arm Attachment	Yes	Yes	Identical in size and construction
HipAttachment	Yes	Yes	Identical in size and construction
Number of Inflatable appliance segments	4	4	Identical
Weight	5.7 pounds	5.8 pounds	Similar
Dimensions (W x H x D)	11.25” x 5.1” x 6.7”	10” x 6.5” x 5”	Similar
Housing Materials and Constructions	Molded ABS enclosure	Molded ABS enclosure	Identical
Patient contact	Non-conductive appliances	Non-conductive appliances	Identical
Safety Features	Button on display allows user to stop or pause therapy session at any time.	Button on display allows user to stop or pause therapy session at any time.	Identical
Modes	2 Modes: “A” mode inflates and deflates chambers from bottom to up (distal to proximal chambers), one at a time “B” mode also inflates from bottom up, but maintains pressure in lower chambers as it works it way to the top. Then all chambers release pressure at the same time once all chambers have sequentially inflated	2 Modes: “A” mode inflates and deflates chambers from bottom to up (distal to proximal chambers), one at a time “B” mode also inflates from bottom up, but maintains pressure in lower chambers as it works it way to the top. Then all chambers release pressure at the same time once all chambers have sequentially inflated	Identical

Reference Device: Pressure Therapy System PT1003 - 510(k) K181409

510(k) Summary

Substantial Equivalence Discussion

In the above detailed table we have compared the ProPerformance Recovery System to the predicate for equivalence of:

Indications –

The Speed Hound ProPerformance Recovery System 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 Speed Hound Recovery System simulates kneading and stroking of tissues by using an inflatable garment.

These indications are identical to the predicate.

Prescriptive – The ProPerformance Recovery System is OTC as is the predicate

Design, Technology and Principle of Operation – The ProPerformance Recovery System have equivalent design and features when compared to the predicate and have identical technology to the predicate

Performance and Specifications – The ProPerformance Recovery System have equivalent specifications of performance when compared to the predicate.

Compliance with standards – The predicate devices declares compliance with IEC 60601-1 and IEC 60601-1-2. The ProPerformance Recovery System complies with AAMI ANSI ES6060-1 (which replaced IEC 60601-1), IEC 60601-1-11 for home use and IEC 60601-1-2.

Materials –

The patient contacting materials of the ProPerformance Recovery System are the inflatable garments which are identical to the reference device Pressure Therapy System PT1003 - 510(k) K181409.

Patient Population –

The ProPerformance Recovery System and predicates are indicated for adults

Environment of Use –

The ProPerformance Recovery System and predicates are for use in clinics, hospital, athlete training, and home environments.

Differences –

There are no differences between the proposed device and the predicate device that raise any new safety and efficacy concerns.

510(k) Summary

Performance Testing

Bench:

The device has been tested to insure that it all requirements have been met, this includes:

- Testing of all controls
- Testing of all indicators
- Testing of performance

See **Sections 16** and **18** for test reports for the above.

The device has also been tested to the requirements of the following standards:

- AAMI / ANSI ES60601-1:2005 + A1: 2012 Medical electrical equipment - part 1: general requirements for basic safety and essential performance

- IEC 60601-1-2: 2014 Collateral standard: Electromagnetic Disturbances - Requirements and Tests

- IEC 60601-1-11: 2015, Collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment

See **Section 17** for test reports for the above.

Animal:
No animal testing was performed

Clinical:
No clinical testing was performed

Differences –
There are no differences between the proposed device and the predicate device that raise any new safety and efficacy concerns.

12.2 Substantial Equivalence Rationale

The ProPerformance Recovery System is viewed as substantially equivalent to the predicate device because:

Indications – are identical to the predicate

Prescriptive – The ProPerformance Recovery System and predicate are OTC.

510(k) Summary

Design, Technology and Principle of Operation – The ProPerformance Recovery System has equivalent design and features when compared to the predicate and have the identical technology to the predicate.

Performance and Specifications – The ProPerformance Recovery System has equivalent specifications of performance when compared to the predicate.

Compliance with standards – The predicate device is compliant with IEC 60601-1 and IEC 60601-1-2. The ProPerformance Recovery System complies with AAMI ANSI ES6060-1 (which replaced IEC 60601-1) and IEC 60601-1-2. Additionally the ProPerformance Recovery System complies with IEC 60601-1-11 for home healthcare.

Materials – The patient contacting materials of the ProPerformance Recovery System are the inflatable appliances they are identical to the predicate.

Environment of Use – Clinics, hospital, athlete training, and home environments s, not specified for predicate but predicate is OTC.

Features - The ProPerformance Recovery System has equivalent features when compared to the predicate.

Conclusion
The ProPerformance Recovery System ise substantially equivalent to the predicate in: indications for use, patient population, environment of use, technology characteristics, materials, specifications / performance and compliance with international standards. Minor differences as detailed in the substantial equivalence table above do not raise questions of safety and effectiveness.